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VIA FEDERAL EXPRESS

Mark B. McClellan, M.D., Ph.D., Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: CMS-1270-P -- Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues

Dear Dr. McClellan:

Abbott welcomes the opportunity to comment on the Centers for Medicare & Medicaid Services' ("CMS") proposed rule to implement the Medicare durable medical equipment ("DME"), prosthetics, orthotics, and supplies ("DMEPOS") competitive bidding program ("Proposed Rule").

Abbott is a global, broad-based health care company devoted to discovering new medicines, new technologies and new ways to manage health. Our products span the continuum of care, from medical devices and nutritional products through laboratory diagnostics and pharmaceutical therapies. The company employs 65,000 people and markets its products in more than 130 countries.

The Proposed Rule is of particular interest to two Abbott divisions – Abbott Diabetes Care and the Ross Products Division. Abbott Diabetes Care manufactures diabetes care products, including self-monitoring blood glucose ("SMBG") systems, test strips, data management software, and accessories that help individuals with diabetes obtain the diagnostic information they need to control their disease. Through effective self-monitoring of blood glucose levels, individuals can take charge of their day-to-day diabetes care by adjusting medications, diet, and/or activity levels to achieve optimal diabetes self-management. The Ross Products Division is a dedicated leader in the research and development of specialized enteral nutritional products, which provide therapeutic nutritional support to patients who cannot swallow and/or digest and absorb adequate nutrition from traditional nutrient sources. Integrating the appropriate enteral nutritional intervention into care plans is essential to the health outcomes of patients with severe and chronic diseases like cancer, HIV/AIDS, chronic obstructive pulmonary disease ("COPD"), diabetes, and kidney disease. In most cases, enteral nutritionals are the prime source of the individual's nutrition, and the beneficiaries depend on the enteral products to live.

Abbott fully supports the Congressional goals of promoting high-quality care for Medicare beneficiaries while achieving improved management of costs, and we believe that the Proposed Rule must ensure that it balances both of these key Congressional objectives. We also agree with Congressional drafters of the competitive bidding statute that the program

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needs to be phased in judiciously, both geographically and through careful selection of products for inclusion in each phase of bidding. We are very concerned, however, that the proposed DMEPOS competitive bidding rule is overly broad and does not comply with Congressional directives to tailor competitive bidding in a way that protects the quality of care for Medicare beneficiaries. CMS's Proposed Rule could restrict beneficiary access to medically-necessary blood glucose monitoring and enteral nutrition products, resulting in adverse impacts on patient health care outcomes.

Our specific concerns and recommendations are highlighted in our Executive Summary and discussed in greater detail in our comments below. We appreciate the opportunity to offer constructive comments on how to structure competitive bidding in a way that will protect the availability of medically-necessary diabetes and enteral products, ensure beneficiary choice of home medical equipment suppliers, and promote high quality care for Medicare beneficiaries.

Executive Summary: Abbott's Comments on Proposed Competitive Bidding Rule

1. CMS should exercise the authority granted by Congress to select only those products for competitive bidding that will achieve congressional goals of cost control and continued availability of high quality DMEPOS for Medicare beneficiaries and that have been successfully tested in a competitive bidding demonstration. Enteral nutrition and blood glucose monitoring systems represent two categories of products that CMS should exclude from competitive bidding.

   As discussed in detail in our comments, blood glucose monitoring products should be excluded because:

   - It would limit access to medically-necessary blood glucose monitoring equipment, which would compromise the beneficiary's ability to control his or her blood glucose levels, increase the risks of serious adverse impacts, and even jeopardize the patient's life.
   - These products have never been tested in a competitive bidding demonstration, and the impact on patient outcomes has not been assessed; and
   - It would not achieve cost savings, since complications associated with inappropriate diabetes care would result in higher overall health care costs for the Medicare program.

   Likewise, enteral nutrition products should be excluded from competitive bidding because:

   - They are the beneficiary's sole source of nutrition, and necessary for the Medicare beneficiary to survive. If a patient does not have adequate access to specific enteral products, it could have an adverse clinical impact on the patient's overall health status and jeopardize patient safety.

- Enteral products were found in Phase I of the Polk County demonstration to be "not as well-suited for competitive bidding" as other types of DMEPOS tested.[1]

- The majority of Medicare enteral nutrition patients reside in skilled nursing facilities, which raises distinct clinical, quality, and operational issues that have not been successfully tested or resolved.

2. If CMS considers including blood glucose monitoring or enteral nutrition products in any future phase of competitive bidding, we recommend that CMS:

   - First do so on a limited basis in a single competitive bidding area ("CBA") in order to monitor the impact on beneficiary care and ensure certain key operational issues are resolved, as discussed below,

   - Include only products furnished in the home care setting (i.e., not products furnished in the skilled nursing facility setting);

   - Establish appropriate subcategories to preserve access to blood glucose monitoring products with medically-necessary and distinct features, and require suppliers to include in their bids certain medically-necessary item features within the enteral product codes;

   - Exclude from competitive bidding those specially-formulated enteral nutritional products (B4153, B4154, and B4155) that are designed for beneficiaries with a particular medical condition, since there is a serious medical risk associated with inappropriate substitutions of the disease-specific formulas in this category; and

   - Include enteral equipment in the grandfathering process, clarify that CMS intends to establish separate payment amounts for each enteral nutritional product and supply HCPCS code (rather than a bundled payment), and maintain current enteral pump rental payment policy.

3. We recommend that CMS establish final supplier quality standards and ensure that suppliers are accredited before implementing bidding in any region.

4. We recommend that CMS adopt retail supplier proximity standards based on the Part D prescription drug program pharmacy access standards to preserve adequate patient access to medically-necessary blood glucose monitoring systems and enteral nutritionals, equipment, and supplies.

5. We support the voluntary, rather than mandatory, use of mail order suppliers.

6. We support CMS's proposed requirement that suppliers fill prescriptions with the brand or mode of delivery specified by the physician or prescribing clinician.

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1 Evaluation of Medicare's Competitive Bidding Demonstration for DMEPOS, Final Evaluation Report, prepared by the Center for Health Systems Research and Analysis and RTI International, November 2003, at 252.

7. We recommend that CMS exclude the bids of limited service DMEPOS suppliers (e.g., SNFs and physicians), mail order suppliers, and unaccredited suppliers when establishing pivotal bids and single payment amounts to promote fair and realistic pricing determinations and ultimately ensure beneficiary access to an adequate number of suppliers.

8. We recommend that CMS establish payment amounts in the first phase of competitive bidding after excluding outlier bids, and test alternatives to the use of the median price (e.g., mean and weighted mean).

9. We recommend that CMS not apply competitive bidding prices outside of competitive bidding areas until the results of the first phases of competitive bidding are fully assessed, the mandated reports have been submitted, and a separate rulemaking with public comment period is issued to adopt a suitable framework for the policy.

10. CMS should issue a separate rulemaking if it seeks to refine the current "gap fill" pricing methodology, and should not adopt "functional technology assessments" as currently proposed.

Detailed Comments: Table of Contents

Abbott's Detailed Comments on Proposed DMEPOS Competitive Bidding Rule

I. Comments Related to Blood Glucose Monitoring Products

A. Legal and Policy Rationale for Exclusion of Blood Glucose Monitoring Products [Criteria for Item Selection]

Abbott Recommendation: CMS should exercise the authority granted by Congress to select only those products for competitive bidding that will achieve the Congressional goals of cost control and continued availability of high quality DMEPOS for Medicare beneficiaries. Moreover, CMS should include in the first phase of competitive bidding only those products that have been successfully tested in prior competitive bidding demonstrations. Because blood glucose monitoring products have not been tested at all, and because inclusion of these products could compromise quality of care for beneficiaries with diabetes, CMS should not include blood glucose monitoring products in the first phase of the competitive bidding program. If CMS considers including blood glucose monitoring products in any future phase of competitive bidding, we recommend that CMS first do so on a limited basis in a single competitive bidding area in order to monitor the impact on beneficiary care and ensure certain key operational issues are resolved.

1. Overview of Statutory Authority for Limitation of Products in Competitive Bidding

The Medicare Modernization Act of 2003 ("MMA") authorizes CMS to select products from within three statutory categories of DMEPOS to include in various CBAs. The MMA does not mandate that all products in these categories be included in competitive bidding. To the contrary, the MMA gives the Secretary considerable flexibility in establishing which products will be included in each area. Specifically, the MMA provides that CBAs "may differ for different items and services," recognizing that all products will not be included in bidding. CMS acknowledges this authority in the Proposed Rule, stating that it "may elect to phase in some individual product categories in a limited number of competitive bidding areas in order to test and learn about their suitability for competitive bidding."[2]

The MMA also expressly excludes certain products from competitive bidding. In the related legislative history, Congress notes that it is excluding from competitive bidding certain products because they "sustain or support life . . . or present potential unreasonable risk . . . ."[3] While this legislative history pertains specifically to Class III devices, it also identifies a Congressional intent to exclude from competitive bidding certain products that raise significant patient safety concerns, and this intent should guide CMS in selecting products for competitive bidding. Abbott demonstrates in detail below that certain Medicare beneficiaries rely on specific blood glucose monitoring products to sustain or support life.

For instance, approximately half of individuals on dialysis have diabetes. They depend on blood glucose monitoring systems that avoid what the Food and Drug Administration ("FDA")

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2 71 Fed. Reg. 25,670.

3 Conference Report to Accompany MMA Report, 108-391 at page 575.

characterizes as the "potential for life-threatening falsely elevated glucose readings" in the presence of certain dialysis solutions since it can be life-threatening if the falsely elevated glucose reading is treated with aggressive insulin therapy. As explained by an FDA advisory[4]:

> We recently received a report of a patient who suffered irreversible brain damage following an aggressive insulin treatment that was given for elevated glucose readings. Unfortunately, the elevated glucose readings were incorrect because the glucose monitoring device, which was unable to distinguish between glucose and maltose, was reacting to the maltose in the intravenous immunoglobulin solution that the patient was receiving.

Competitive bidding for these products would present an unreasonable risk of adverse clinical impact. There clearly are unique, patient-critical operational issues associated with blood glucose monitoring products, stemming from the complex therapeutic needs of the Medicare beneficiaries with diabetes and the need to protect access to certain medically-necessary product features, among others. Using Congress' own standards for exclusion, blood glucose monitoring products should be excluded from competitive bidding.

In addition, under section 1847(b)(7), in a section entitled "Consideration in Determining Categories for Bids," Congress recognized the need to take into account clinical issues and the impact on patient care in determining products to be included in bidding. Specifically, the statute provides the following:

> (7) CONSIDERATION IN DETERMINING CATEGORIES FOR BIDS.—The Secretary may consider the clinical efficiency and value of specific items within codes, including whether some items have a greater therapeutic advantage to individuals.

CMS should exercise this statutory authority to exclude certain blood glucose monitoring products from the initial phase of competitive bidding that have greater therapeutic advantages for individuals. Such products include: those that prevent interference from such substances such as aspirin, uric acid, vitamin C, and acetaminophen; those that prevent falsely elevated glucose readings in dialysis patients receiving certain dialysis solutions, those that have multiple body site testing capabilities; and those that require small blood sample size and therefore minimize pain associated with testing. The therapeutic advantages of these products are discussed below.

CMS also has the statutory authority to exclude products from competitive bidding if "the application of competitive acquisition is not likely to result in significant savings." As we discuss below, inclusion of blood glucose monitoring products would not achieve cost savings, since complications associated with inappropriate diabetes care would result in higher overall health care costs for the Medicare program, and thus they can and should be excluded from competitive bidding.

If CMS decides to include any blood glucose monitoring products in Phase I, it should be done on a limited basis (i.e., one initial CBA) to ensure that CMS adequately addresses these operational issues in a way that protects the quality of care of beneficiaries with diabetes.

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4 http://www.fda.gov/cdrh/oivd/news/glucosefalse.html.

2. Blood Glucose Monitoring Supplies and Equipment Were Not Tested in Competitive Bidding Demonstrations

CMS should include in the first round of competitive bidding only those products that have been successfully tested in a prior competitive bidding demonstration project to ensure that CMS has adequate information regarding the impact of competitive bidding on patient access, medical outcomes, and beneficiary satisfaction. We note that CMS lists as a factor it will consider when determining whether a product is appropriate for competitive bidding the "Savings in the DMEPOS Demonstrations" associated with that product.[5] We agree with CMS that this is an important factor for consideration in product selection.

CMS did not include blood glucose monitoring systems in the DMEPOS demonstration. We believe that CMS had strong policy and patient care reasons for not including blood glucose monitoring products in the demonstration; those reasons still apply. Equally important, CMS has no experience with the impact inclusion of such products would have on beneficiary care or overall health care spending. While the products that were included in the Polk County and San Antonio demonstrations generated a great deal of data, including information on beneficiary satisfaction, access to products, pricing, and supplier capacity issues, and this information has been subject to evaluation and careful review by CMS, its contractors, and the public, such data is completely lacking for blood glucose monitoring products.

CMS therefore should not include blood glucose monitoring products in the first phase of the competitive bidding program. Instead it would be more prudent for CMS to concentrate on those products that were successfully tested in the previous demonstrations. If CMS decides to include blood glucose monitoring systems in any future phase of competitive bidding, it should first test its impact on a limited scale (i.e., in one CBA).

3. Complexity of Diabetes Patient Care Needs

According to the American Diabetes Association ("ADA"), diabetes is one of the nation's most debilitating, deadly, and costly diseases. There currently are 20.8 million Americans – or 7 percent of the population – with diabetes, and the pace of new cases is increasing. More than 10 million individuals age 60 years or older, or 20.9 percent of all people in this age group, have diabetes. Diabetes is the leading cause of kidney disease, adult-onset blindness, and lower limb amputations and a significant cause of heart disease and stroke. Diabetes contributed to 224,092 deaths in 2002. The mortality rate due to diabetes has increased by 45 percent since 1987 – at the same time the mortality rates due to heart disease, stroke, and cancer have actually declined.[6] Effective management of diabetes – including monitoring and regulating blood glucose levels – is key to preventing numerous serious complications, including blindness, kidney and nerve damage, diabetic ketoacidosis, hyperosmolar (nonketotic) coma, and even death.[7]

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5 71 Fed. Reg. 25,671.

6 American Diabetes Association, available at www.diabetes.org.

7 (ADA, 2005). See also the DCCT Trial and the United Kingdom Prospective Diabetes Study ("UKPDS").

Proper glucose monitoring requires careful selection of the meters and strips that are medically appropriate for the beneficiary's condition, taking into account the patient's comorbidities, interfering substances, and other health factors (such as visual impairments) that could affect the choice of a particular system. There currently are more than 30 blood glucose monitoring systems on the market. As discussed below, among these systems there are a wide range of capabilities and features, including advanced features designed to meet very specific patient health care needs. Blood glucose monitoring systems are not interchangeable, and clinicians need to determine and prescribe the features that best meet that patient's needs, considering comorbidities and other health factors.

For instance, some blood glucose monitoring systems are unsafe for use by individuals on dialysis because they provide falsely elevated glucose readings in patients receiving dialysis solutions containing maltose or galactose, or oral d-xylose. The FDA has warned that there have been serious injuries and even deaths from false glucose readings in these situations that have lead to overly aggressive insulin therapy.[8] In fact, the FDA has posted many safety alerts on this issue, as recently as November 2005. The agency requires the package insert for these types of glucose monitoring systems to include a warning such as "Peritoneal dialysis solutions containing icodextrin cause overestimation of glucose test results" or "Patient receiving peritoneal dialysis using solutions containing icodextrin (e.g., Extraneal®, Icodial) should not use [this product]." Because approximately 50 percent of patients on dialysis have diabetes, it is critical that patients using these dialysis solutions in each CBA have access to blood glucose monitoring systems that minimize or eliminate interference with these solutions, such as monitoring systems that use GDH-NAD or glucose oxidase. Other blood glucose monitoring systems prevent interference from such substances such as aspirin, uric acid, vitamin C, and acetaminophen, each of which can distort blood glucose readings for patients with such conditions as arthritis or gout. Beneficiaries in each CBA need to be able to access blood glucose monitoring systems that are unaffected by these common agents.

If CMS includes blood glucose monitoring systems in competitive bidding, it could limit access to blood glucose monitoring equipment with a greater therapeutic advantage to individuals, which would compromise the beneficiary's ability to monitor and control his or her blood glucose levels, increase the risks of serious adverse impacts, and even jeopardize the patient's life. We therefore recommend that CMS exercise its statutory authority to not include blood glucose monitoring systems in competitive bidding.

8 See http://www.fda.gov/cber/safety/maltose110405.htm.

4. Interference with Coordinated Care/Chronic Care Demonstration

According to CMS itself, "Fragmentation of care is a serious problem, especially for Medicare beneficiaries," who on average see seven different physicians and have 20 prescriptions each year.[9] The difficulties of coordination of care for individuals with diabetes, and its impact on health care outcomes, also have been documented in a recent series in the *New York Times*. For instance, one recent article pointed out that "a study last year by Georgetown University found that insurance restrictions on strips and other services for diabetics were reducing the quality of care." The same article also quoted an 82-year old individual with diabetes who observed that "Controlling my condition isn't that hard. . . The hard part are the things outside my control, like getting the test strips and the medicines."[10]

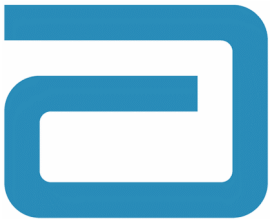
The problems associated with fragmentation of care for diabetes patients and the need to carefully manage the diabetes and comorbidities of Medicare beneficiaries is the reason the federal government has included diabetes care in its major chronic care demonstration project. Specifically, the MMA authorized the development and testing of voluntary chronic care improvement programs, now called Medicare Health Support programs, to improve the quality of care and life for people living with multiple chronic illnesses. The programs are designed to help participants adhere to their physicians' plans of care and obtain the medical care they need to reduce their health risks, while providing savings to the Medicare program and beneficiaries. CMS selected beneficiaries with diabetes and/or congestive heart failure for inclusion in the Medicare Health Support program because they "have heavy self-care burdens and high risks of experiencing poor clinical and financial outcomes," and because of the prevalence of comorbidities. CMS notes that evidence indicates that "self-care support, education, and assistance in coordinating care for people with these conditions can be effective in improving clinical outcomes, reducing their healthcare costs, and improving participant and provider satisfaction."[11] The Medicare Health Support programs are operated by organizations that were chosen by CMS through a competitive selection process. CMS has not discussed in the proposed rule how restricting beneficiary choice of suppliers or pharmacists through DMEPOS competitive bidding would impact coordination of care for Medicare beneficiaries with diabetes who are participating in Medicare Health Support programs. Moreover, CMS does not discuss how DMEPOS competitive bidding would affect the pay-for-performance approach established through the Medicare Health Support program, under which fees to organizations are based on meeting standards for quality improvement, savings to Medicare, and increased satisfaction levels in their assigned beneficiary populations – outcomes that could be affected by the restrictions imposed by competitive bidding. Likewise, CMS does not address how competitive bidding could undermine CMS's ability to evaluate the effectiveness of the Medicare Health Support programs for beneficiaries who live in DMEPOS CBAs.

More broadly, CMS should consider the adverse impact of competitive bidding on coordination of care for patients with diabetes, both for beneficiaries enrolled in the Medicare Health Support program and for beneficiaries who coordinate their care through their clinicians, pharmacists, and other caregivers. For instance, Medicare beneficiaries who are enrolled in

9 See http://www.cms.hhs.gov/CCIP/02_Highlights.asp.

10 Urbina, Ian; "In the Treatment of Diabetes, Success Often Does Not Pay," New York Times, January 11, 2006.

11 See http://www.cms.hhs.gov/CCIP/downloads/MHSOverview012306.pdf.



Medicare Part D may receive their oral medications, insulin, and syringes – along with pharmacist counseling -- through their pharmacy. Including blood glucose monitoring products in competitive bidding could further fragment care for this population.

5. Limited Potential for Cost Savings

According to the ADA, one out of every 10 health care dollars is spent on diabetes and its complications. Direct and indirect spending on diabetes care reached $132 billion in 2002, $40.3 billion of which was spent for inpatient hospital care and $13.8 billion for nursing home care for people with diabetes. Cardiovascular disease accounted for more than $17.6 billion of the direct medical costs for diabetes in 2002. Studies have shown that frequent testing and tighter control of blood glucose levels can dramatically reduce the adverse consequences of diabetes.[12]

Competitive bidding risks jeopardizing beneficiary access to the most appropriate blood glucose meters and strips, which could make it more difficult for beneficiaries to control their diabetes, leading to increased complications and costly hospital care.[13] In fact, in a June 2006 report to Congress, the Medicare Payment Advisory Commission ("MedPAC") points out that "longer term savings could come from improved management of conditions such as diabetes because poor glucose control in diabetics can lead to worse cardiovascular health in the longer term."[14] CMS clearly has the statutory authority to exclude from competitive bidding those products "for which the application of competitive acquisition is not likely to result in significant savings." Given the potential for increased Medicare costs – particularly Part A hospital costs – resulting from complications associated with inappropriate diabetes care, CMS should undertake an assessment of the potential financial impact on the Medicare program related to diabetes complications prior to including such products in competitive bidding.

B. Significant Clinical and Technological Distinctions of Blood Glucose Monitoring Products – Risk of Limiting Access to Medically-Necessary Features [Physician Authorization/ Treating Practitioner; Conditions for Awarding Contracts]

Abbott Recommendation: CMS should preserve access to products with medically-necessary features. If CMS includes blood glucose monitoring products in any future phase of competitive bidding, CMS should exercise its statutory authority to establish separate subcategories within codes for bidding purposes to recognize blood glucose monitors and strips with advanced features (e.g., those that prevent interference from such substances such as aspirin, uric acid, vitamin C, and acetaminophen; those that are safe for use by beneficiaries undergoing dialysis; those that have multiple body site

12 *See, e.g.*, Karter et al., "Self-Monitoring of Blood Glucose Levels and Glycemic Control: the Northern California Kaiser Permanente Diabetes Registry," 111 Am. J. Med. 1 (2001).

13 Agency for Healthcare Research and Quality, Economic and Health Costs of Diabetes (2005).

14 MedPAC "Report to the Congress: Increasing the Value of Medicare" (June 2006).

testing capabilities, and those that require small blood sample size and therefore minimize pain associated with testing, increasing compliance and improving health outcomes). CMS should either exclude the advanced subcategories from bidding or require suppliers to bid on all subcategories. Moreover, bidding suppliers should only supply blood glucose monitoring systems that offer beneficiaries 24/7 manufacturer support.

There is only one HCPCS code for all blood glucose test strips (A4253 Blood Glucose Test or Reagent Strips for Home Blood Glucose Monitor, per 50 Strips), and one blood glucose meter HCPCS code (E0607 -- Home blood glucose monitor) that encompasses almost all of the meters currently on the market. These codes have been in place for over 15 years. During this time, meter and strip technologies have changed significantly, and now there are important features that improve accuracy and promote testing compliance. Particular features of products within these codes provide a greater therapeutic advantage to individuals, including preventing potentially life-threatening false readings in the presence of interfering substances.

The MMA provides CMS with the authority to establish separate subcategories for items within HCPCS codes if the clinical efficiency and value of items within a given code warrants a separate category for bidding purposes. Specifically, the statute provides the following:

> CONSIDERATION IN DETERMINING CATEGORIES FOR BIDS.—The Secretary may consider the clinical efficiency and value of specific items within codes, including whether some items have a greater therapeutic advantage to individuals.

In a number of situations, there are blood glucose monitoring systems that provide a clear therapeutic advantage to individuals, such as by preventing false glucose level readings that could lead to ineffective or potentially harmful medical interventions. For instance, some blood glucose monitoring systems are unsafe for use by individuals on dialysis because they provide falsely elevated glucose readings in patients receiving dialysis solutions containing maltose or galactose, or oral d-xylose. There have been serious injuries and even deaths from false glucose readings in these situations that have lead to overly aggressive insulin therapy. In addition, beneficiaries using acetaminophen for arthritis or gout must use blood glucose monitoring systems with low or negligible interference from acetaminophen or they could receive inaccurate glucose level information and subsequently make inappropriate or harmful treatment decisions. Also, it is now well established that patients with diabetes have elevated uric acid levels; many systems using glucose oxidase are severely affected by elevated uric acid levels. Likewise, ascorbic acid (vitamin C) in elevated doses is widely used by many consumers, yet it can interfere with some glucose monitoring systems. Other systems provide therapeutic advantages because they have multiple body site testing capabilities or require smaller blood sample size, thereby minimizing pain associated with testing and enhancing beneficiary compliance with testing regimens.

Beneficiaries and their clinicians must have access to the most clinically-appropriate blood glucose monitoring system for their conditions. Given the proposed bidding structure, there is a real risk that suppliers seeking to submit a competitive bid may choose not to offer advanced equipment and supplies – unless compelled to do so – because of concerns that their bids will not be low enough to be selected, which would jeopardize their opportunity to serve beneficiaries in the bidding area. Beneficiary access to these therapeutically and clinically necessary features could then be compromised.

Therefore, if blood glucose monitoring products are included in any future stage of competitive bidding, CMS should exercise its authority to protect patients by establishing subcategories within the blood glucose meter and test strip HCPCS codes to recognize these advanced features, and either: (1) exclude the advanced systems from competitive bidding, or (2) require suppliers to submit separate bids for each subcategory. Our recommendations for subcategories are presented below. We recommend that CMS establish a public review and comment period regarding any subcategories it develops.

Moreover, in recognition of the unique and critically-important role of manufacturer education and technical support for patients using blood glucose monitoring systems, we recommend that CMS require that suppliers may only submit bids for any category or subcategory of blood glucose monitors or test strips if the products offer 24-hour/7-day-a-week manufacturer support. Unlike many other segments of the DMEPOS industry, education of and technical support for patient using blood glucose monitoring systems ideally is performed by the manufacturer, rather than by the DMEPOS supplier. As noted, there currently are more than 30 blood glucose monitoring systems available to suppliers and beneficiaries. A single supplier simply cannot know the technical intricacies of every monitoring system. Such manufacturer-specific knowledge is critical, since a misunderstanding or misinterpretation of results could lead to erroneous treatment decisions resulting in adverse health outcomes (such as the potentially deadly administration of too much insulin). A single manufacturer can receive between *75,000 and 100,000 calls from patients, caregivers, and health care providers in a single month*. Manufacturers of high-quality blood glucose monitoring systems like Abbott have intensely-trained professionals that provide technical support and professional guidance on how to operate the equipment, including responding to questions and concerns in multiple languages. These staff members are trained to distinguish between user and technical errors, and to assist beneficiaries with their questions and concerns regarding effective management of their diabetes, and often encourage patient follow-up with their health care providers. Not every manufacturer offers these critical services, however. There is a danger that under the competitive bidding framework, there will be an incentive for suppliers to bid on the least expensive products within a code, even if the manufacturers of these products do not provide comprehensive patient support for their products. This would not promote quality of care for Medicare beneficiaries, a key goal of lawmakers in the MMA. Therefore, if CMS includes blood glucose monitoring products in any future phase of competitive bidding, it should specify in its request for bids that that suppliers may only submit bids for blood glucose monitors or test strips if the products offer 24-hour/7-day-a-week manufacturer support. CMS or its contractors should provide suppliers with a list of eligible equipment under this requirement.

Recommendations for Subcategories

We recommend that CMS establish the following subcategories within codes A4253 (Blood Glucose Test or Reagent Strips for Home Blood Glucose Monitor, per 50 Strips), and E0607 (Home Blood Glucose monitor) if these products are included in any future phase of competitive bidding:

HCPCS	Descriptor	Subcategory	Descriptor
A4253	**Blood Glucose Test or Reagent Strips for Home**	A	Protection Against Interfering Substances

	Blood Glucose Monitor, per 50 Strips		
		B	Safe with Commonly-Used Dialysis Solutions
		C	Small blood sample size – 1.0 microliter or less
		D	Blood samples accessed from multiple/alternative body sites
		E	Aids for Visual Impairments
		F	Testing Alarms
E0607	**Home Blood Glucose Monitor**	A	Protection Against Interfering Substances
		B	Safe with Commonly-Used Dialysis Solutions
		C	Small blood sample size – 1.0 microliter or less
		D	Blood samples accessed from multiple/alternative body sites
		E	Aids for Visual Impairments
		F	Testing Alarms

CMS should either: (1) exclude these advanced systems from competitive bidding, or (2) require suppliers to submit separate bids for each subcategory. Additional information regarding the clinical efficiency, value, and therapeutic advantages of these products follows.

1. Protection Against Interfering Substances

Blood glucose monitoring systems vary in their ability to minimize interference from certain common substances, such as aspirin, acetaminophen used for arthritis or gout treatment, elevated uric acid levels, or ascorbic acid (vitamin C) in elevated doses. Interference effects may result from relatively high voltages applied to the blood glucose test strips, interference from oxygen, or enzyme interactions. For instance, some strips, including the FreeStyle™ Blood Glucose Monitoring Strip, use glucose dehydrogenase -- rather than on glucose oxidase -- as an enzymatic catalyst during its reaction with glucose. Unlike glucose oxidase, oxygen is not involved in the reaction pathway of glucose dehydrogenase, and therefore interference by oxygen – a problem with older technology devices – is substantially reduced.

If test results are distorted by the inability of a blood glucose monitoring system to minimize interference from these common substances, it could lead to inappropriate treatment decisions that could have an adverse impact on beneficiary health. CMS therefore should establish a subcategory of meters and test strips that minimize interference and either exclude this subcategory from competitive bidding, or require suppliers to bid separately on the subcategory.

2. Safe with Commonly-Used Dialysis Solutions

Blood glucose monitoring and safety of patients undergoing dialysis is particularly important because approximately fifty percent of all dialysis patients have diabetes. The FDA has warned, however, that certain blood glucose monitoring systems provide falsely elevated

glucose readings in patients receiving certain dialysis solutions. These falsely-elevated glucose readings can be life-threatening if they result in inappropriately aggressive insulin therapy. Serious injuries and deaths from such false glucose readings have occurred.

In November 2005, the FDA issued an alert entitled "Important Safety Information on Interference With Blood Glucose Measurement Following Use of Parenteral Maltose/Parenteral Galactose/Oral Xylose-Containing Products.[15] In light of the "potential for life-threatening falsely elevated glucose readings," the FDA warns that patients who receiving products containing the sugars maltose or sugars which are metabolized to maltose should "[u]se only test methods not affected by the presence of maltose, galactose, or d-xylose, such as glucose dehydrogenase nicotine adenine dinucleotide (GDH-NAD), glucose oxidase- or glucose hexokinase-based test methods."

Beneficiaries undergoing dialysis in every CBA must have available blood glucose monitoring systems that have been determined by the FDA to be safe for use by peritoneal dialysis patients. CMS should either exclude from competitive bidding blood glucose monitoring systems that are safe for use with commonly-used dialysis solutions, or establish a subcategory for these meters and strips and require suppliers to bid separately to supply meters and strips that are safe for this population.

3. Small Blood Sample Size – 1.0 Microliter or Less

Certain strips require a smaller sample size (for example the FreeStyle system requires approximately 0.3 microliter of blood, compared to as much as 4 to 5 microliters in older meters). The smaller volume is obtained by a less invasive blood draw mechanism that lowers pain, which is a major barrier to regular blood testing for people with diabetes. This improved technology encourages regular testing and good glucose monitoring and control. In addition, a smaller blood sample requirement can reduce the need for retests due to the meter registering "insufficient blood." The FDA reports[16] that users whose meters require less blood would have this insufficient blood retest problem less often – avoiding strip wastage. Likewise, some monitoring systems can measure the adequacy of the collected blood sample size, which ensures that the test starts only when enough blood has been collected, which again minimizes errors and retests and decreases costs associated with wasted strips. Beneficiaries in every CBA need access to blood glucose monitoring systems with this feature.

15 See http://www.fda.gov/cber/safety/maltose110405.htm.

16 FDA, "Glucose Meters & Diabetes Management" (http://www.fda.gov/diabetes/glucose.html).

4. Blood Samples Accessed from Multiple/Alternative Body Sites

Some blood glucose monitoring systems, including the FreeStyle system, can effectively access samples from multiple body sites with fewer nerve endings per square inch than the fingertips. Therefore testing can be done using less painful sites like forearms, upper arms, thighs and calves. The greater flexibility in sites from which blood can be drawn, with lower pain thresholds, promotes patient compliance with testing. Studies have shown that frequent testing and tighter control of blood glucose levels can dramatically reduce the adverse consequences of diabetes.[17]

5. Aids for Visual Impairments

Some blood glucose monitors provide verbal instructions and results for safe and effective testing by individuals with vision impairment. Many users perform glucose tests in dim light condition. A monitor (such as the FreeStyle Flash) that has a backlit display and a test light illuminating the test strip area can help reduce test errors and decrease costs associated with wasted strips.

6. Testing Alarms

Adherence to blood glucose monitoring is a challenge for some patients. Certain monitors (such as the FreeStyle Flash and FreeStyle Freedom) allow the user to program up to four daily alarms to remind them to test. As previously noted, frequent testing and tighter control of blood glucose levels can dramatically reduce the adverse consequences of diabetes.

C. Conditions for Awarding Contracts/Market Demand and Supplier Capacity

Abbott Recommendation: CMS should ensure that beneficiaries have adequate access to retail suppliers. Mail order suppliers should not skew CMS's capacity calculations in a competitive bidding area. CMS should not overestimate the ability of blood glucose monitoring system suppliers to expand capacity. CMS should exclude bids from mail order suppliers in determining the pivotal bid and single payment amounts since mail order suppliers would not be subject to the same initial delivery, set-up, and beneficiary education/training requirements as other suppliers.

CMS should preserve beneficiary access to retail suppliers and pharmacies. Indeed, blood glucose monitoring products are available at over 50,000 pharmacies nationwide. Beneficiaries rely on their pharmacies to assist in the management of their total diabetes care needs, including treatment for the comorbidities that so often accompany diabetes. Competitive bidding should not disrupt this important network for beneficiaries

CMS is proposing that beneficiaries have a choice of at least two suppliers in a bidding area. We are concerned that two suppliers for a large CBA could be insufficient to provide beneficiaries with adequate access to a retail pharmacy. Instead, we propose that CMS apply

17 *See, e.g.*, Karter et al., "Self-Monitoring of Blood Glucose Levels and Glycemic Control: the Northern California Kaiser Permanente Diabetes Registry," 111 Am. J. Med. 1 (2001).

its Part D retail pharmacy access standards to the DMEPOS competitive bidding program. These standards have been an important protection for beneficiaries enrolled in Part D, and offer a tested framework for the competitive bidding program to adopt. Specifically, under the Part D program, drug plans must establish retail pharmacy networks as follows (with certain limited exceptions):

- Urban areas -- At least 90 percent of the Medicare enrollees in the drug plan's service area must, on average, live within two miles of a network retail pharmacy;
- Suburban areas -- At least 90 percent of the Medicare enrollees in the plan's service area must, on average, live within five miles of a network retail pharmacy; and
- Rural areas -- At least 70 percent of the Medicare enrollees in the plan's service area must, on average, live within 15 miles of a network retail pharmacy.

While a Part D plan's pharmacy network may be supplemented by non-retail pharmacies, including pharmacies offering home delivery via mail-order, these pharmacies do not count towards fulfilling the plan's pharmacy access requirements. We recommend adopting such a model under DMEPOS competitive bidding. Thus, If CMS decides to allow mail order suppliers to bid in DMEPOS competitive bidding, those mail order suppliers should not count towards the two-supplier minimum that CMS is establishing in each CBA.

CMS also should give greater weight to retail suppliers when determining supplier capacity to ensure that the presence of mail order suppliers does not reduce the number of retail suppliers available to a beneficiary. This is particularly important since the draft DMEPOS quality standards state that mail order services may not be used "for the initial delivery, set-up, and beneficiary education/training for certain DME equipment and supplies," and CMS must ensure that beneficiaries have adequate access to retail suppliers who can supply these critical services.

In the preamble to the Proposed Rule, CMS asserts that "most DMEPOS suppliers would be able to easily increase their total capacity to furnish items by up to 20 percent and the increase could be even larger for products like diabetes supplies that require relatively little labor." We believe CMS is misinformed regarding the labor required to furnish appropriate blood glucose monitoring supplies, and we are concerned that this could lead CMS to approve fewer diabetes suppliers in a bidding area than is truly necessary to adequately meet beneficiary demand. Under the draft DMEPOS supplier standards, diabetes suppliers must provide extensive beneficiary services, including meeting detailed standards regarding product delivery, set-up, training, equipment usage and cleaning, and troubleshooting. The supplier also is responsible for follow-up services, including continuing communication with the treating physician or clinical team regarding outcomes of monitoring, maintenance, and operation of all equipment provided to the beneficiary; periodically reviewing the service plan with the treating physician or clinicians regarding the beneficiary's medical condition and the continued use and tolerance of the equipment and supplies; and communicating any clinically significant beneficiary concerns, needs, and condition changes that affect the beneficiary's use of equipment and supplies to the treating physician within 24 hours of determination. CMS should recognize these important diabetes supplier responsibilities and ensure that there is sufficient supplier capacity to meet beneficiary needs.

CMS does not discuss how, if it contracts with mail order suppliers, it would consider mail order bids in determining the pivotal bid and single payment amounts. We believe it is obvious that CMS could not to consider mail order suppliers' bids in the same pool as retail supplier bids, since mail order suppliers would not be subject to the same initial delivery, set-up, and beneficiary education/training requirements as other suppliers. In fact, mail order suppliers would be prohibited from providing these services under the draft DMEPOS supplier standards. Because mail order suppliers would not be providing the same level of beneficiary service, their bids would reflect lower costs than those of retail suppliers. Any comparison of the two types of bids (retail and mail order) would be particularly unfair to small retail suppliers, and could lead to inappropriate payment policies and capacity determinations. CMS should develop standards for the separate consideration of mail order bids before including mail order suppliers in competitive bidding.

We also want to point out that CMS should consider the impact of its policies on supplier capacity beyond the Medicare population. CMS envisions dramatically fewer suppliers being able to provide services to Medicare patients since there will be relatively few winning bidders. Suppliers that are not successful bidders may no longer have the demand to support their ability to continue furnishing supplies in the competitive bidding area to Medicaid and private paying patients. This could reduce the availability of critical health care services to vulnerable patient populations, particularly individuals with diabetes.

D. Competitive Bidding Areas/Nationwide or Regional Mail Order Competitive Bidding

Abbott Recommendation: We support the voluntary, rather than mandatory, use of mail order suppliers.

Many beneficiaries with diabetes obtain their medical supplies and insulin through one of the 50,000 pharmacies that supply blood glucose monitoring products. Access to pharmacies is important for beneficiaries in managing their total diabetes care needs, including treatment for the comorbidities that so often accompany diabetes. Mandating the use of mail order suppliers for blood glucose monitoring supplies would prevent beneficiaries with diabetes from using one source to coordinate the pharmaceuticals, medical supplies, and equipment necessary to manage their complex medical conditions. Moreover, pharmacies and other retail suppliers can play an important role in continuing beneficiary education, training, and troubleshooting regarding their blood glucose monitoring equipment, a role that would be jeopardized by mandating mail-order replacement of supplies. Mail order suppliers would not be able to provide timely care if a beneficiary needs emergency refills. We therefore do not believe that "furnishing replacement test strips, lancets or other supplies can easily, effectively, and conveniently be performed by national mail order suppliers," as CMS stated in the preamble, and we urge CMS to reject this proposal.

If CMS decides to allow mail order suppliers to participate in competitive bidding, we recommend that it be voluntary for beneficiaries – just as CMS has provided under the Part D prescription drug benefit. Moreover, CMS should ensure that all appropriate DMEPOS quality standards are met, including that the mail order suppliers furnish products and supplies that are consistent with the clinician's order, meet the product specifications as prescribed by the clinician, and that qualified staff are available to respond to beneficiary concerns and needs.

II. Comments Related to Enteral Nutrition Equipment and Supplies

A. Legal and Policy Rationale for Exclusion of Enteral Products [Criteria for Item Selection]

Abbott Recommendation: CMS should exercise the authority granted by Congress to select only those products for competitive bidding that will achieve Congressional goals of cost control and continued availability of high quality DMEPOS for Medicare beneficiaries. Moreover, CMS should include in the first phase of competitive bidding only those products that have been successfully tested in prior competitive bidding demonstrations. Because enteral products were found in Phase I of the Polk County demonstration to be "not as well-suited for competitive bidding" as other types of DMEPOS tested, and because inclusion of these products could compromise quality of care for beneficiaries who rely on enteral nutrition, CMS should not include enteral nutrition products in the first phase of the competitive bidding program.

1. Overview of Statutory Authority for Limitation of Products in Competitive Bidding

As previously noted, the MMA authorizes CMS to select products from within three statutory categories of DMEPOS to include in various CBAs. The MMA does not mandate that all products in these categories be included in competitive bidding. Instead, the MMA gives the Secretary considerable flexibility in establishing which products will be included in each area. Specifically, the MMA provides that competitive bidding areas "may differ for different items and services," recognizing that all products will not be included in bidding. CMS notes this authority in the Proposed Rule, stating that it "may elect to phase in some individual product categories in a limited number of competitive bidding areas in order to test and learn about their suitability for competitive bidding."[18]

The MMA also expressly excludes certain products from competitive bidding. In the related legislative history, Congress notes that it is excluding from competitive bidding certain products because they "sustain or support life . . . or present potential unreasonable risk . . . ."[19] While this legislative history pertains specifically to Class III devices, it also identifies a Congressional intent to exclude from competitive bidding certain products that raise significant patient safety concerns, and this intent should guide CMS in selecting products for competitive bidding. Abbott demonstrates in detail below that certain Medicare beneficiaries rely on enteral products to sustain or support life because they are the beneficiary's sole source of nutrition. If a patient does not have access to specific enteral products, it could compromise the patient's health, accelerate the disease process, and in serious cases lead to medical complications that could endanger the patient's life (i.e., aspiration resulting from incorrect feeding, inappropriate nutritional provided for a particular disease state). Competitive bidding for these products would present an unreasonable risk of adverse clinical impact. Using Congress' own standards for exclusion, enteral products should be excluded from competitive bidding.

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18 71 Fed. Reg. 25,670.

19 Conference Report to Accompany MMA Report, 108-391 at page 575.

Moreover, there apparently was confusion among the Congressional authors of the MMA's competitive bidding provision regarding the status of enteral products under competitive bidding. As CMS is aware, unlike most products in DMEPOS categories (e.g., orthotics, wheelchairs, hospital beds, etc.), enteral nutrition is covered as a prosthetic – a medical product that replaces all or part of a malfunctioning internal body organ.[20] A House Ways and Means Committee press release issued at the time of MMA passage states that the competitive bidding statute: "Exempts all prosthetics and implantable (Class III) devices" (emphasis added).[21] Lawmakers were mindful of the special safeguards needed to protect beneficiaries that rely on prosthetic devices that sustain and support life, and they concluded that the competitive bidding framework was inappropriate for these critical products. Thus, it is appropriate and consistent with Congressional intent for CMS not to include enteral products in competitive bidding.

In addition, under section 1847(b)(7), in a section entitled "Consideration in Determining Categories for Bids," Congress recognized the need to take into account clinical issues and the impact on patient care in determining products to be included in bidding. Specifically, the statute provides the following:

> (7) CONSIDERATION IN DETERMINING CATEGORIES FOR BIDS.—The Secretary may consider the clinical efficiency and value of specific items within codes, including whether some items have a greater therapeutic advantage to individuals.

As discussed below, certain enteral nutritionals have a greater therapeutic advantage to individuals with certain medical conditions. For instance, some specialized medical nutritional products are specially formulated to meet the unique nutritional and therapeutic needs of patients with chronic disease states, such as cancer, HIV/AIDS, kidney disease, pulmonary disease, Crohn's disease, and diabetes, and it would threaten a beneficiary's health and life if they did not have reasonable access to a supplier that could furnish their particular life-sustaining nutritional. Other enteral nutritionals are designed for patients with pressure ulcers, multiple fractures, wounds, burns, or surgery who have depressed immune mechanisms and rely on these products for wound healing and immune support. CMS should recognize the unique clinical nature of these products and their important role in comprehensive chronic disease care plans by excluding them from competitive bidding.

The MMA also provides statutory authority to phase in competitive bidding based on "items and services that the Secretary determines have the largest savings potential," and to completely exclude products from competitive bidding if "the application of competitive acquisition is not likely to result in significant savings." Inclusion of enteral products would not

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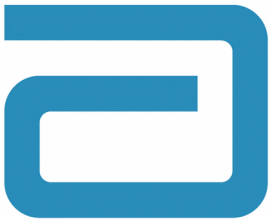
20 Medicare National Coverage Determinations Manual (CMS Pub. 100-03), §180.2 - Enteral and Parenteral Nutritional Therapy, "Coverage of nutritional therapy as a Part B benefit is provided under the prosthetic device benefit provision which requires that the patient must have a permanently inoperative internal body organ or function thereof."

21 Ways and Means Committee, "Medicare Prescription Drug, Improvement, and Modernization Act of 2003 -- Medicare DME Freeze And Competitive Bidding Saves Beneficiaries and Taxpayers Money," available at http://waysandmeans.house.gov/media/pdf/healthdocs/dmesummary.pdf.



achieve cost savings, since complications associated with inappropriate enteral care could result in higher overall health care costs for the Medicare program.
Research consistently shows that malnutrition – a state of inadequate or unbalanced nutrition – is a hidden cause of poor health outcomes and rising health care costs in the United States. There are also many studies that confirm the benefits of nutrition intervention including decreased morbidity and mortality, improved quality of life, and decreased length of stays and care costs. American Dietetic Association studies show that for every $1.00 spent on nutrition intervention, at least $3.25 is saved. Continuous monitoring and assessment of a patient's nutrition status is essential in the prevention of major complications like anemia, bone fusion failure, wound and joint infection, pressure ulcers, septicemia, pulmonary embolus, pneumonia, and others that add significant health care costs to the system. Competitive bidding risks jeopardizing beneficiary access to the most appropriate enteral nutrition products and services, which could interrupt care plans resulting in increased hospital admissions and increased home nursing services (covered under Medicare Part A). In addition, the prevalence of Medicare enteral use among nursing home patients and the strong case for excluding nursing homes from competitive bidding (detailed below) diminishes the potential for cost savings by including enteral products from competitive bidding, as the final DMEPOS demonstration project evaluation report concluded.

2. Complexity of Patient Care Needs

The proposed competitive bidding structure – which could result in dramatically fewer suppliers, diminished patient choice of suppliers, and decreased access to a range of medically-necessary items and services -- could have a particularly significant and negative impact on clinically-intensive patients who rely on enteral nutrition.

Unlike most products in DMEPOS categories (e.g., orthotics, wheelchairs, hospital beds, etc.), enteral nutrition is covered as a prosthetic – a medical product that replaces all or part of a malfunctioning internal body organ. Enteral nutrition is necessary for the Medicare beneficiary to survive. Thus, enteral products have both a distinct statutory Medicare benefit category and a unique clinical role as a beneficiary's sole source of nutrition.

Enteral nutrition is the delivery of necessary calories, nutrients, and other therapeutic ingredients through a tube placed into the gastrointestinal ("GI") tract (either directly into the stomach or through the small intestine), bypassing the mouth. Enteral nutrition is used by patients who have a disease or non-function of the structures that normally permit food to reach the small bowel, or a disease which impairs digestion and absorption of an oral diet. It is essential for patients who cannot swallow and/or digest and absorb adequate nutrition from traditional nutrient sources and for patients who are at risk of malnutrition. These patients include those patients with cancer, HIV/AIDS, stroke, multiple sclerosis, cerebral palsy, Parkinson's Disease, Amyotrophic Lateral Sclerosis, diabetes mellitus, liver failure, chronic renal failure, inflammatory bowel disease, among many others. Tube feeding is vital to sustain these patient's lives and to address their special medical needs. This is most often the individual's only form of nutrition, and choosing the specific enteral nutrition intervention strategy and integrating it with medical, surgical, and pharmacologic care is crucial to the overall health status of a beneficiary.

As recognized in the draft DMEPOS quality standards, beneficiaries using enteral products are subject to a wide range of complications from tube feeding, including constipation and nausea/vomiting, persistent or progressive abdominal pain, cramping, bloating, fullness or

burning with feedings, infections, and leakage around the tube. Moreover, patients using enteral feeding often have comorbidities that complicate patient care, such as pressure sores, pneumonia, anemia, and infections. Serious metabolic complications like hypertonic or isotonic dehydration or overhydration can occur if the fluid and electrolyte status of a tube-fed patient is not monitored closely and correctly. Mechanical problems also are often associated with some aspect of the feeding tube itself: tube size, material, or location of the GI tract. For example, aspiration pneumonia, a potentially lethal mechanical complication, may occur from compromise of the lower esophageal sphincter by a large-caliber feeding tube or from dislodgment or misplacement of the feeding tube. Thus, the complex clinical nature of enteral nutrition is different than other conventional DME, orthotics, and commodity supplies.

When a beneficiary is placed on enteral nutrition, the clinician must determine the most appropriate site and access route for feeding based on patient-specific factors such as the physiology of the GI tract, risk of pulmonary aspiration of gastric contents (entry of gastric contents into the lungs during breathing), comorbidities, and the length of time enteral support will likely be needed. The clinician then must assess which products, including formula and in some cases nutrients, pumps, and tubes, are most effective for the individual patient's situation. Each patient has individualized nutrition needs, and there are several formula characteristics the clinician needs to consider, including complexity of nutrients (some formulas contain nutrients in their complex forms, while others have nutrients that are in a simpler form (predigested) for patients who have absorption problems), osmolality, caloric density (calorically dense formulas can be used for patients with fluid restrictions, fluid intolerance, or high energy requirements), micronutrient content (electrolytes, vitamins, minerals and trace elements), fiber, lactose, viscosity, and water content.

As discussed in greater detail below, there is a range of enteral products available within the same HCPCS code, but many of those products are designed for distinct patient needs and are not interchangeable. If a patient does not have access to specific enteral products, it could compromise the patient's health, and in serious cases could lead to a progressive decline in their condition and ultimately endanger the patient's life. Yet under the Proposed Rule, a supplier would only need to furnish one product within a HCPCS code. As a result, products designed for specific diseases could simply be unavailable through contract suppliers in a particular area, creating a gap in the availability of life-sustaining products. Before competitive bidding could be applied to enteral products, CMS would need to establish a mechanism to ensure that each product necessary for a patient's disease state, physiology, or other medical condition is available to the beneficiary in every locality.

A distribution system based on a competitive bidding methodology and low bid incentives also does not adequately recognize the intense supplier services required by the fragile patient population using enteral equipment. Compared to the provision of other DMEPOS products, enteral suppliers are responsible for detailed caregiver and beneficiary education, including steps to resolve common feeding problems, assembly, use, storage and maintenance of all equipment and supplies, cleaning the gastrostomy/jejunostomy site, setting up and cleaning equipment, and recognition and appropriate response to various types of complications, proper tube positioning; formula storage and safety; and problems associated with tube feedings. Because enteral formulas are rich media for promoting microbial growth, all enteral feeding systems require meticulous care. Enteral nutrition patients often require other DMEPOS items and services associated with the patient's underlying medical condition and

comorbidities; restricting access to suppliers based on the lowest cost would fragment patient care and could have a negative impact on medical outcomes.

Given that these products sustain and support life and have an extensive service component, we are concerned that competitive bidding could result in inadequate pricing for products. This would present an unreasonable risk that patients would not have access to needed enteral products and quality care. CMS therefore should use its statutory authority to exclude enteral products from competitive bidding.

If CMS nevertheless does not exclude all enteral products from competitive bidding, CMS should: (1) limit inclusion initially to a single CBA to ensure that CMS adequately addresses these operational issues in a way that protects the quality of care of beneficiaries using enteral nutrition products; (2) limit competitive bidding to enteral products in the home care setting (rather than in a SNF); (3) exclude specialized nutrients designed for disease-specific and patient-specific needs from competitive bidding; (4) ensure that product are included within certain HCPCS codes to reflect the clinical efficiency and value of certain features; and (5) and address certain other operational issues, as discussed below.

3. Enteral Products were Shown to be "Not Well Suited" for Competitive Bidding in Prior Demonstration

When Congress enacted the MMA, it appears lawmakers believed that the competitive bidding demonstrations were a complete success. For instance, according to the House Ways and Means Committee, "Competitive Bidding Demonstration Was Successful," and under the first round of contracts, "Access to quality equipment was maintained" and "beneficiary satisfaction remained high." Likewise, CMS states in the preamble to the proposed rule that "The competitive bidding demonstrations . . . were implemented successfully in both demonstration sites from 1999 to 2002, resulted in a substantial savings to the program and offered beneficiaries sufficient access and a quality product."

However, these assessments fail to distinguish the results for enteral nutritional products from the other tested products. CMS included enteral nutrition products in phase one of the Polk County demonstration. The Final Evaluation of Medicare's Competitive Bidding Demonstration for DMEPOS prepared by the Center for Health Systems Research and Analysis and RTI International concluded that enteral nutrition "is not as well-suited for competitive bidding" as other products tested. Moreover, under the first round of the competitive bidding demonstration, beneficiary satisfaction ratings for enteral nutrition and surgical dressings decreased the most, and unadjusted impacts were "fairly large and negative" for these products, according to the evaluation report. Indeed, because of the high volume of use of enteral products in the nursing home setting, rather than the home setting where other DMEPOS items are predominantly delivered, CMS did not include enteral products in subsequent rounds of competitive bidding demonstrations in order to concentrate on DME in non-institutional settings.

CMS states that one of the factors it will consider when determining whether a product is appropriate for competitive bidding is whether it has been successfully tested in a competitive bidding demonstration. In light of the negative evaluation enterals products received in the Polk County demonstration, CMS should not include enteral products in competitive bidding unless the agency successfully tests it in a limited area (i.e., one CBA) and sufficient

operational safeguards are in place to promote beneficiary satisfaction and ensure quality of care.

B. Limitation on Scope of Enteral Products [Criteria for Item Selection, Submission of Bids under the Competitive Bidding Program, & Physician Authorization/Treating Practitioner]

Abbott Recommendation: If CMS considers including enteral nutrition products in any phase of competitive bidding, we recommend that CMS:

(1) Do so only on a limited basis in a single competitive bidding area in order to monitor the impact and potential adverse impacts on beneficiary health, and only after adequate quality standards and other operational safeguards are in place;

(2) Add as a criteria for item selection those products used primarily in the home care setting (i.e., not in a skilled nursing facility setting), just as CMS adopted in two of the three rounds of the competitive bidding demonstration project;

(3) Exclude from competitive bidding those specially-formulated enteral nutritional products (B4153, B4154, and B4155) that are designed for beneficiaries with a particular medical condition, since there is a serious medical risk from inappropriate substitutions of formulas in this category; and

(4) Exercise its statutory authority to require suppliers to guarantee access to enteral products with specific medically-necessary features.

1. Single Competitive Bidding Area

If CMS includes enteral products in any phase of competitive bidding, there are unique, patient-critical operational issues that must be addressed, stemming from the complex therapeutic needs of the Medicare beneficiaries who rely on these products, the significant use of enteral product in the skilled nursing facility setting; the need to preserve access to specialized nutritional formulas; the patient-specific nature of selecting the appropriate specialized enteral nutrients, and the need to protect beneficiary access to certain enteral equipment and supplies with medically-necessary product features. Because enteral nutrition was not successfully tested in a previous demonstration, CMS needs to ensure that it develops a framework that adequately addresses the problems encountered in the demonstration and preserves access to specialized formulas and equipment. Thus if CMS decides to include enteral products in any phase of competitive bidding, it should do so first in a single competitive bidding area to ensure that CMS adequately addresses these operational issues in a way that protects the quality of care and safety of beneficiaries using enteral nutrition products.

2. Limit Competitive Bidding to Home Care Setting: Unique SNF Site-of-Care and Patient Severity of Illness Issues

As we discuss in greater detail below, unlike most other items of DME that may be subject to competitive bidding, enteral nutrition can be covered under Part B in the SNF setting in addition to the home care setting. Indeed, approximately 60 percent of Medicare enteral nutrition patients reside in SNFs.

CMS is proposing to require SNFs to participate in competitive bidding or contract with a winning supplier in order to furnish DMEPOS to their residents. However, competitive bidding has not been successfully tested in the nursing home setting, and the pilot failed to show significant savings. Moreover, the clinical needs of patients using enteral products in SNFs, the CMS quality standards, and the mechanism of distribution of products in the SNF are quite distinct from the home care setting. We therefore recommend that CMS not include SNFs initially in competitive bidding, and the agency should carefully consider the following issues before expanding competitive bidding to include SNFs.

a. Level of Care in a SNF Different than for Home Care Patients

Medicare patients in the SNF setting are often medically-complex with multiple comorbidities, particularly compared to beneficiaries in the home setting. Their need to be in a SNF is based on multiple clinical conditions and diagnoses, physical limitations, and need for assistance with activities of daily living. Beneficiaries receiving enteral nutrition rely heavily on the healthcare services that accompany the delivery of the enteral nutrition. In fact, the need for enteral nutrition is a qualifier for the "Clinically Complex" category under Medicare Part A prospective payment system rates. The services needed by SNF patients are considerably different than patients in the home care setting, and their treatment plans must be carefully managed and coordinated by their SNF. That is why the Joint Commission on Accreditation of Healthcare Organizations ("JCAHO") publishes separate Standards for Tube Feeding for different sites of care, including the home care setting and the SNF setting. Including enteral products for patients in the SNF setting could seriously interfere with established and functioning care plans, which could result in medical complications that increase overall costs of care to the Medicare program

b. CMS Has Not Successfully Tested Including Products Furnished to Institutional Patients in Competitive Acquisition

Although CMS included enteral products in the first round of the Polk County competitive bidding demonstration, beneficiaries living in SNFs could receive these products from nondemonstration suppliers that accepted the demonstration fee schedule. CMS did not include enteral products in subsequent rounds of competitive bidding demonstrations in order to concentrate on DME in non-institutional settings. The Final Evaluation of Medicare's Competitive Bidding Demonstration for DMEPOS prepared by the Center for Health Systems Research and Analysis and RTI International concluded that enteral nutrition "is not as well-suited for competitive bidding" as other products tested. Moreover, under the first round of the competitive bidding demonstration, beneficiary satisfaction ratings for enteral nutrition and surgical dressings decreased the most, and unadjusted impacts were "fairly large and negative" for these products, according to the evaluation report. We are concerned that in the

Proposed Rule, CMS characterizes the demonstrations as successful without noting that the negative evaluation of the inclusion of enteral products.

Under the Proposed Rule, CMS is proposing a different framework for including SNFs in competitive bidding than was tested in Polk County. SNFs would be mandated to use a winning supplier. This specific mechanism has not been tested before, so CMS has no data on its impact on beneficiary care. Before CMS considers extending competitive bidding to enteral products furnished in the institutional setting, the concept should be successfully tested in a more limited environment.

c. Competitive Bidding Could Jeopardize SNF Control over Beneficiary Care

Due to the level of services SNFs provide, they operate with higher fixed costs than home medical equipment companies, which could compromise their ability to submit competitive bids to maintain care of their residents. If a SNF is not a winning bidder, it could force the SNF to contract with a third-party for services they handle themselves today, creating inefficiencies in nursing home care. In addition, SNFs would be restricted in contracting with the most appropriate suppliers to help manage the patient's total care needs, including DMEPOS, drugs, and medical and ancillary services – even though the SNF is ultimately responsible for the quality of care furnished to the resident. Including SNFs in competitive bidding also could complicate continuity of medical care for patients, especially if a patient must change suppliers when they move from Part A to Part B coverage. It also could disrupt current SNF contracts with third-party suppliers, since SNFs often contract with one supplier for all medical supply products for all patients. If a SNF's exclusive supplier is not a successful bidder, the entire contractual arrangement for all necessary supplies could be jeopardized. This could create inefficiencies and increase administrative burdens – contrary to the goals of competitive bidding.

d. The Draft DMEPOS Supplier Quality Standards Do Not Fully Apply to Institutional Settings

The draft DMEPOS supplier quality standards recognize the different service requirement expected for suppliers of enteral nutrition, equipment, and supplies depending on whether the supplier is furnishing products in the home setting, in an institutional setting, or under a home health agency ("HHA") plan of care. In fact, the draft standards exempt from the extensive enteral-specific quality standards those suppliers furnishing enterals in a SNF setting or to HHA patients. Specifically, the draft standards provide that:

> If the beneficiary does not receive home health services or does not reside in a SNF, the supplier shall provide qualified staff trained in enteral nutrition to implement beneficiary education, clinical monitoring, and follow-up.

Thus, SNF suppliers are not subject to the full range of quality standards. Yet, under the MMA, Congress mandates that any supplier participating in competitive acquisition must comply with the Medicare supplier quality standards – not just subsets of the standards. Specifically, Section 1847(b)(2) provides that:

(A) IN GENERAL.—The Secretary may not award a contract to any entity under the competition conducted in an competitive acquisition area pursuant to paragraph (1) to furnish such items or services unless the Secretary finds all of the following:

(i) The entity meets applicable quality standards specified by the Secretary under section 1834(a)(20).

Likewise, in the explanation of the conference report, the conferees emphatically state that "the Secretary cannot award contracts in an area until the following conditions were met: (1) entities meet quality standards established by the Secretary. . . ." Because CMS does not apply the full range of supplier quality standards to enteral products furnished in the SNF setting, CMS likewise should not – and indeed is not authorized under the MMA – to apply competitive acquisition to enteral products furnished in the SNF setting.

e. Different Service, Business Structures, and Operations Requirements in SNFs Versus Home Setting Could Compromise Bids

Under the Proposed Rule, enteral suppliers could be subject to one of three different sets of quality standards: (1) the draft DMEPOS general and enteral product-specific supplier standards (including a requirement that the supplier provide qualified staff trained in enteral nutrition for beneficiary education, clinical monitoring, and follow-up) would apply to home care suppliers; (2) the draft DMEPOS general supplier standards – but not the enteral product-specific supplier standards -- would apply to suppliers serving SNF patients under arrangement with the facility; and (3) the current stringent SNF conditions of participation would apply to SNFs that bid to provide enterals to their own patients. If enteral products furnished to SNF patients are included in competitive bidding but are subject to very different quality requirements, bidders would have widely different service-related costs. It is unclear how suppliers would be able to submit realistic bids under the competitive acquisition program, since supplier's mix of services provided to beneficiaries in institutional settings versus the home care setting could be difficult to forecast. Indeed, this situation could have the unintended effect of jeopardizing access to enterals for home care patients, since suppliers might be encouraged to seek out patients that are not subject to the extensive servicing requirements for home enteral products established under the Medicare supplier quality standards – even though the nursing home patients have higher overall acuity levels. A uniform payment rate may be inappropriate in this situation. CMS needs to develop a way to determine equitable bidding and payment policies before including SNFs in competitive bidding.

3. Specialized Enteral Nutrients (B4153, B4154, and B4155) are Inappropriate for Competitive Bidding Framework and Should Be Excluded

Although we believe that CMS should not include any enteral nutritional products in the first round of competitive bidding, it is critical for CMS to exclude specialized nutrient products from competitive bidding (HCPCS codes B4153, B4154, and B4155).

While nutritionally-complete standard medical nutritionals are appropriate for some patients, other patients have medical conditions that require the use of specialized medical nutritional products. Products in these categories are specially formulated to meet the unique nutritional and therapeutic needs of patients with chronic disease states, such as cancer, HIV/AIDS,

pressure ulcers, kidney disease, pulmonary disease, Crohn's disease, diabetes, and severe burns. Only three HCPCS codes encompass this wide and diverse array of nutrients. Products within these categories are clearly not interchangeable. Feeding an inappropriate product within this category to a patient can lead to a cascade of dangerous medical complications that worsen a patient's condition, accelerate the disease process, and in some cases result in death. It would threaten a beneficiary's health and life if they did not have reasonable access to a supplier that could furnish their particular life-sustaining nutritional.

Under the proposed competitive bidding framework, a supplier would only need to furnish one product within a HCPCS code. This would not work for codes B4153, B4154, and B4155, since suppliers could choose to offer a single product in each code that helps beneficiaries with one disease state, but is useless or even dangerous for other beneficiaries that depend on other nutritional in these categories. There could even be a situation where no contract suppliers bid to supply a particular nutritional that is critical for a beneficiary's health and life.

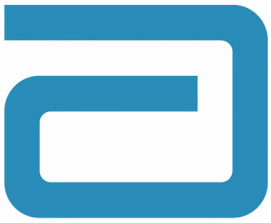
The unique patient benefits provided by the products in codes B4153, B4154, and B4155 are detailed below:

B4153 (Enteral Formula, Nutritionally Complete, Hydrolyzed Proteins (Amino Acids and Peptide Chain), Includes Fats, Carbohydrates, Vitamins and Minerals, May Include Fiber, Administered Through an Enteral Feeding Tube, 100 Calories = 1 Unit)

Hydrolyzed protein elemental formulas are nutritionally complete formulations that are made for patients with vastly different acute and chronic conditions, ranging from tolerance issues like malabsorption and maldigestion, to metabolically-stressed patients that are immunosuppressed and have elevated energy and protein needs. Some products in this category contain simpler nutrients, peptides, and free amino acids that use the dual protein absorption system of the gut for patients with chronically impaired gastrointestinal function. Many patients rely on these products as their sole source of nutrition, and they are the only thing the patients can digest. Other products in this category are designed for patients with pressure ulcers, multiple fractures, wounds, burns, or surgery who have depressed immune mechanisms and rely on these products for wound healing and immune support. Without these products, which not only contain the partially-hydrolyzed, peptide-based protein for easier absorption but are also calorically dense and high in protein, these patients would not be able to heal.

B4154 (Enteral Formula, Nutritionally Complete, For Special Metabolic Needs, Excludes Inherited Disease Of Metabolism, Includes Altered Composition of Proteins, Fats, Carbohydrates, Vitamins and/or Minerals, May Include Fiber, Administered Through an Enteral Feeding Tube, 100 Calories = 1 Unit)

The nutritionally-complete products in this category are as different as the metabolic conditions for which they are used. These products have customized caloric distribution formulated specially to meet the needs of patients with conditions such as kidney disease and chronic kidney failure; metabolic stress resultant from acute injury, surgery or chronic disease; pulmonary disease; diabetes; HIV/AIDS; and cancer. Products in this



category are not interchangeable; in fact, substituting different products within these codes designed for different diseases could be detrimental to the patient and the condition being treated. Lack of access to any of these products can compromise the health of a patient and will impact quality of care. For instance, feeding a patient with a chronic respiratory condition (i.e., COPD) a product that is designed for someone with kidney disease who is not yet being treated with dialysis would provide a protein level that is too low as well as a carbohydrate level that is too high, causing excess carbon dioxide. Due to their lack of lung function and inability to fully respirate, this could result in toxic levels of carbon dioxide in the blood stream, leading to hospitalization. On the other hand, another product in this category specially designed for pulmonary patients would provide such patients with the clinically-appropriate levels of carbohydrates to ensure controlled carbon dioxide production and concentrated calories and protein in order to maintain low volumes of fluid consumed, a major concern for the respiratory patient. Likewise there are products in this category that are specifically designed for individuals with kidney disease being managed without dialysis. Feeding a product designed for people with diabetes to this patient would provide excessive protein and an inappropriate renal solute load that might compromise their already-impaired renal function.

B4155 (Enteral Formula, Nutritionally Incomplete/Modular Nutrients, Includes Specific Nutrients, Carbohydrates (e.g., Glucose Polymers), Proteins/Amino Acids (e.g., Glutamine, Arginine), Fat (e.g., Medium Chain Triglycerides) or Combination, Administered Through an Enteral Feeding Tube, 100 calories = 1 unit)

Products within this category are nutritionally incomplete but contain specific nutrients that address very different patient needs. For instance, one product is designed to provide an easily-digested source of carbohydrate calories for patients with increased caloric needs that cannot be consumed in food but who are on a fat-restricted diet. Another product is a therapeutic nutritional that contains a patented blend of arginine, glutamine and HMB (beta-hydroxy-beta methylbutyrate) clinically proven to help build lean body mass, enhance immune response, and promote collagen synthesis in patients with advanced stages of pressure ulcers. This product also has been shown to replenish weight in the form of lean body mass or functional tissue, not fat mass, and supports immune function in patients with HIV/AIDS.

Because of the specialized nature of these products, Medicare currently requires the patient's medical record to adequately document the specific condition and the need for the specially formulated nutritional. Products in these categories represent those that are developed according to the most current nutritional recommendations, and they contain specialized formulations of ingredients as well as patented ingredients in some products. Excluding these product categories from competitive bidding would ensure beneficiary access to the appropriate specialized products.

In addition to the strong clinical reasons for excluding specialized nutritionals from competitive bidding, CMS also has authority to exclude these products under its statutory authority to exclude products that would not result in significant savings. Current Medicare spending on

products in these categories represent only 2% of total enteral nutrition spending in home setting and only 7% in all settings. (Based on 2004 CMS BESS Procedure Data). In view of the highly diversified needs of patients using these products, we do not expect competitive bidding to result in significant savings for this class of products. Since enteral nutrition sustains and supports life, and unreasonable risks could result from disruption in access, this class of products meets Congressional standards for exclusion and thus should be excluded from bidding.

If CMS nevertheless decides to include codes B4153, B4154, and B4155 at any stage of competitive bidding, CMS would need to ensure that beneficiaries in every CBA had access to products within each code that are appropriate for their distinct medical conditions or therapeutic needs. Because each product within these three codes is uniquely formulated and appropriate use is dependent on varying combinations of patient-specific factors, the development of subcategories within these codes is a complex task. We recommend that CMS work with clinical specialists to develop any such requirements and that there be an opportunity for public comment.

4. Significant Clinical and Technological Distinctions of Enteral Products – The Need to Protect Access to Medically-Necessary Features

Many of the HCPCS codes for enteral nutrition formulas, equipment, and supplies contain products that are not interchangeable, and in many cases have significant differences among them. Differences include a range in technology and features as well as packaging to enhance safety, and particular features may be critical to a patient's medical care. Given the proposed bidding structure, there is a real risk that suppliers seeking to submit a competitive bid may choose not to offer enteral products with such advanced, medically-necessary features unless compelled to do so. Moreover, they may choose to substitute items and base their bids on other devices and supplies not designed for enteral feeding due to concerns that their bid will not be low enough to be selected and they will lose their opportunity to serve Medicare beneficiaries in the bidding area.

The MMA provides CMS with the authority to recognize during the bidding process those products within codes that have enhanced clinical efficiency and value. Specifically, the statute provides the following:

> CONSIDERATION IN DETERMINING CATEGORIES FOR BIDS.—The Secretary may consider the clinical efficiency and value of specific items within codes, including whether some items have a greater therapeutic advantage to individuals.

If enteral products are included in competitive bidding, CMS should exercise this authority to require that suppliers guarantee access to enteral products with certain important features that promote patient safety, as detailed below. Such features should be specified in the bidding instructions, and suppliers should indicate on the bid sheets the exact products they would supply with these features. Moreover, CMS should ensure during its bid review process that any bids for enteral products include only products designed specifically for enteral feeding, since we are aware of some suppliers substituting lower-cost products (such as urinary catheters used as feeding tubes or enema bags used as feeding sets) that are not specifically designed for enteral tube feedings and that can lead to allergic reactions, corrosion of tubing, and adverse patient outcomes.

The following is a discussion of the specific product features that should be available in every CBA.

a. HCPCS Code B4150 (General Purpose Formulas) & B4152 (Calorically Dense Formulas) – Access to Both Can and Pre-Mixed Packaging

Nutritional products within the HCPCS codes B4150 and B4152 are available either in premixed bottles (also called “ready to hang” or “ready to use”) or in cans. Ready to hang products require no handling or pouring of the product. This delivery system is important for product safety (rather than just for beneficiary convenience). Product in cans must be decanted into a feeding set or alternate container, which significantly increases the chances of contamination. Contamination refers to the introduction of bacteria into the product, which increases the risk of spoilage and can cause symptoms of food poisoning (e.g., vomiting and diarrhea), or may introduce infection. These problems may lead to dehydration or sepsis, severely compromising an already debilitated patient. A Hazard Analysis Critical Control Point ("HACCP") analysis concludes that ready-to-use products that do not expose enterals to the air during assembly have lower contamination rates than open systems. HACCP’s “Guidelines for preventing healthcare-associated infections during enteral feeding in primary and community care” therefore recommend that “Wherever possible pre-packaged, ready-to-use feeds should be used in preference to feeds requiring decanting, reconstitution or dilution,” and the “system selected should require minimal handling to assemble, and be compatible with the patient’s enteral feeding tube.”[22] Beneficiaries, their clinicians, and caregivers need access to ready to hang products as appropriate; in fact, some clinical care protocols require the use of such products. Accordingly, CMS should ensure beneficiary access to ready to hang product by requiring suppliers to guarantee access to and availability of ready to hang products within the B4150 and B4152 HCPCS codes.

To ensure patient access to ready to hang packaging, CMS should require suppliers to specify on the bidding sheet that they will supply both can and ready to hang packaging for products in codes B4150 and B4152, and provide such products to the beneficiary in the packaging specified by the patient’s health care professional.

b. HCPCS Code B9002 (Enteral Feeding Pump w/Alarm) – Access to Pumps with Automatic Flush Feature, that are Ambulatory, have Anti-Free Flow Feature, and Lock-Out Option

CMS should require that suppliers guarantee access and availability of enteral pumps with essential features to meet their specific medical needs. The features include:

22 Final Guideline: Prevention of healthcare-associated infections in primary and community care, June 2003.

(1) Automatic Flush. This feature is necessary for patients who need small bore feeding tubes such as jejunostomy tubes and are prone to tube clogging (i.e., patients who use multiple medicines and patients who need to have residuals checked frequently).

(2) Ambulatory. This feature is necessary to allow patients who are not bed ridden to move around with their pump (i.e., get up to use the bathroom).

(3) Anti-free flow. This safety feature prevents inadvertent free flow of product that could result in overfeeding and other inadvertent adverse events.

(4) Lock-out option. This safety feature prevents tampering with pump settings to prevent overfeeding or underfeeding. This feature is necessary for patients with mental disabilities such as Alzheimer and patients with small children in the home.

CMS should specify in the bidding instructions that enteral suppliers must furnish a range of product options within HCPCS code B9002 that include an automatic flush feature, are ambulatory, have an anti-free flow feature, and a lock-out option, and they must provide such products to the beneficiary as specified by the patient's health care professional. Suppliers should indicate on the bid sheets the exact products they would supply with these features.

c. HCPCS Code B4086 (Gastrostomy/jejunostomy tube, any material, any type, standard or low profile) – Access to Safety Features, Designed for Enteral Use

Feeding tubes vary widely in terms of their dimensions, composition, ability to prevent clogging or contamination, among other important features. Beneficiaries need access to the tubing selected by their provider to be safe and medically-appropriate. CMS should ensure through the bidding process that any supplier bidding on enteral tubing agree to furnish tubing with the following features:

(1) Polyurethane and silicone. Tubes may be constructed of various materials, ranging from polyvinyl chloride ("PVC") and latex to polyurethane and silicone tubes. PVC and latex tubes are cheaper than polyurethane and silicone tubes, but they can stiffen and erode from contact with digestive juices, are associated with allergic reactions, and often are not designed specifically for enteral feeding (i.e., some suppliers substitute with foley catheters designed for bladder drainage) Polyurethane and silicone tubes, while more expensive, are the most biocompatible and appropriate for patient care

(2) Radiopaque material. This is necessary to help ensure proper placement of a tube into the stomach or small intestine and x-ray confirmation of tube placement.

(3) Weighted tips. This is necessary to lessen the risk of improper placement and backward migration of the tube, to which some patients may be prone.

(4) Eyelet design, flow-thru tips. This feature is necessary to reduce tube clogging that can result in a premature need for tube replacement.

(5) Y-port/Interlocking connectors. This is necessary to provide an additional port used for flushing the tube and for administering medications without the need to disconnect the feeding set and tube. This helps minimize the risk of touch contamination, which is essential to quality patient care and safety. Another important part of the Y-port connector is the cap that interlocks with the O-ring on the feeding set. An interlocking feature minimizes leakage and potential for inadvertent or accidental separation, which could result in a patient not getting fed appropriately.

(6) Skin disk or external retention hub at the surface of the skin. This is necessary to maintain tube position, decreasing the chance of tube migration inward and minimizing leakage of gastric contents around the tube.

(7) Internal bumper. This is a necessary feature that secures the tube up against the gastric wall to minimize unwanted changes in position and leakage of gastric contents.

CMS should specify in the bidding instructions that enteral suppliers must furnish products within HCPCS code B4086 that are composed of polyurethane and silicone; include radiopaque material; and/or have the following features: weighted tips; include eyelet design/flow-thru tips; Y-port/interlocking connectors; skin disk or external retention hub; and internal bumper. Suppliers must provide such products to the beneficiary as specified by the patient's health care professional. Suppliers should indicate on the bid sheets the exact products they would supply with these features. Moreover, CMS should review the items specified on the bid sheet to ensure that they are designed and manufactured specifically for enteral feeding.

d. HCPCS Code B4081 (Nasogastric tube with stylet) & B4082 (Nasogastric tube without stylet) – Access to Polyurethane Tubes, With or Without Stylet

CMS should require that suppliers guarantee access and availability of nasogastric tubes with specific features to ensure beneficiaries have access to tubes that will meet their specific medical needs. Such features within HCPCS code B4081 and B4082 include:

(1) Polyurethane tubes. Soft, flexible material necessary for both patient comfort and to decrease tube-related complications when placing a tube through the nasal passage for enteral feeding. Tubes made of any other substance (i.e., PVC) become brittle with repeated use, resulting in unnecessary discomfort and tube-related complications for the patient.

(2) Nasoenteric tube with stylet. This is necessary for placement of a soft and flexible small bore tube. The stylet provides the temporary stiffening of the tube during this invasive placement procedure.

CMS should specify in the bidding instructions that enteral suppliers must furnish nasogastric tubes (B4081 and B4082) comprised of polyurethane, and they must provide such products to the beneficiary as specified by the patient's health care professional. Suppliers should indicate on the bid sheets the exact products they would supply with these features. CMS should review the items specified on the bid sheet to ensure that they are designed and manufactured specifically for enteral feeding. Likewise, CMS should require suppliers to furnish nasogastric tubes with or without stylets as specified by the patient's health care professional.

e. HCPCS Code B4035 (Pump Supply Kit), B4034 (Syringe Supply Kit) and B4036, (Gravity Supply Kit) -- Access to Appropriate Feeding Supply Kits

Manufacturers specifically design enteral feeding supply kits (pump, syringe and gravity) to connect to feeding pumps (HCPCS code B9002) and feeding tubes (HCPCS codes B4086, B4081 and B4082) as an integrated system for enteral nutrition delivery. These designs include special interlocking connectors that eliminate the need to tape connectors and decrease the likelihood of inadvertent or accidental separation from the feeding set, which can result in underfeeding and increased risk of leakage and contamination. Manufacturers research and test the use of these integrated systems to ensure both patient safety as well as ease of use, which is particularly important for patients and caregivers in the home setting.

CMS should specify in its bidding instructions that suppliers must use supply kits that are manufacturer-researched and tested to be appropriate for use in an integrated enteral feeding system. Moreover, if a supplier begins servicing a beneficiary that already owns or rents an enteral feeding pump, the supplier must provide the beneficiary with the appropriate supply kit for the beneficiary's specific equipment.

C. Conditions for Awarding Contracts/Market Demand and Supplier Capacity

Abbott Recommendation: CMS should protect beneficiary safety and choice by implementing, at a minimum, the Medicare Part D proximity measures when determining capacity needs for CBAs.

Section 1847(b)(4)(A) provides that in determining the number of suppliers necessary for a CBA, the Secretary shall:

> . . . take into account the ability of bidding entities to furnish items or services in sufficient quantities to meet the anticipated needs of individuals for such items or services in the geographic area covered under the contract on a timely basis.

We are concerned that CMS's proposal to provide as few as two suppliers in a CBA would be insufficient to meet this statutory requirement and to protect beneficiaries who rely on enteral nutrients. Enteral nutrients are the sole source of a beneficiary's nutrients and they play a life-sustaining role in a beneficiary's health care regimen. Since enteral nutrients are the food supply for these beneficiaries, they simply cannot wait for days to receive service from a restricted number of winning suppliers. These beneficiaries also need to have a variety of suppliers in close proximity if an emergency situation arises, such as if an immediate change in products is necessary to sustain life.

Likewise, the delivery of enteral nutrition involves intense supplier services for and consistent routine monitoring of patients using enteral equipment, as discussed above. Beneficiaries using enteral products are subject to a wide range of serious and even life-threatening complications from tube feeding. The complex clinical nature of enteral nutrition is different than other conventional DME, orthotics, and commodity supplies, and suppliers need to be in close proximity to their patients to immediately address complications.

In addition, CMS should respect the close nature of the relationship between the beneficiary and the supplier, and ensure beneficiaries have a choice in which supplier will enter their home to delivery enteral nutrition products. It is critical that these patients feel comfortable with the supplier that will enter their home and stand bedside to educate them on steps to resolve common feeding problems, use, storage, and maintenance of all equipment and supplies; including cleaning the gastrostomy/jejunostomy site and recognition and appropriate response to various types of complications.

Due to the critical nature of enteral nutrition and the need to have suppliers in close proximity to their patients, we recommend that CMS implement as a minimum standard the Medicare Part D proximity measures when selecting suppliers for a CBA. As noted above, the Medicare Part D proximity standards require drug plans to establish retail pharmacy networks as follows (with certain limited exceptions):

- Urban areas -- At least 90 percent of the Medicare enrollees in the drug plan's service area must, on average, live within two miles of a network retail pharmacy;
- Suburban areas -- At least 90 percent of the Medicare enrollees in the plan's service area must, on average, live within five miles of a network retail pharmacy; and
- Rural areas -- At least 70 percent of the Medicare enrollees in the plan's service area must, on average, live within 15 miles of a network retail pharmacy.

Application of the Medicare Part D proximity standards to home care suppliers under the DMEPOS competitive bidding program would help ensure suppliers are close enough in proximity to their patients to service their enteral nutrition needs without an unreasonable travel delay. As in the Part D program where only retail suppliers count toward meeting this

proximity standard, under Part B only home medical equipment suppliers should count towards this minimum number. Likewise, if CMS decides to allow mail order suppliers to bid, those mail order suppliers should not count towards the minimum number of suppliers that CMS is establishing in each CBA, since the draft DMEPOS quality standards limits the services mail order suppliers may provide to beneficiaries.

It is also important for CMS to consider the impact of its policies on supplier capacity beyond the Medicare population. CMS envisions dramatically fewer suppliers being able to provide services to Medicare patients since there will be relatively few winning bidders. Suppliers that are not successful Medicare bidders may no longer have the demand to support their ability to continue furnishing supplies in the competitive bidding area to Medicaid and private paying patients. This could reduce the availability of critical health care services to vulnerable patient populations, particularly patients requiring enteral nutrition. In addition, suppliers that provide enteral products usually have a larger portion of non-Medicare patient populations (i.e., pediatric patients). If there is insufficient DME supplier interest in bidding to supply enteral items for the Medicare population, it could have a negative impact on non-Medicare beneficiary access to critical enteral nutritional items and services.

D. Bidding Requirements/Enteral Nutrition Equipment and Supplies

Abbott Recommendation: If enteral products are included in competitive bidding, CMS should establish separate single payment amounts for enteral nutrients and enteral supplies. CMS should not reduce rental payments for enteral equipment in months 4 through 15.

1. Single Payment Amounts

In the discussion of enteral nutrition equipment and supplies, CMS states that "Based on the bids submitted and accepted for new items, we would calculate a single payment amount for purchase of enteral nutrients and supplies." This language could be read to indicate CMS is contemplating a bundled payment for both nutrients and supplies, although the proposed regulatory text appears to indicate that CMS would establish a single payment amount for purchase of enteral nutrients and a separate single payment amount for supplies. We seek to confirm that if enteral products are included in competitive bidding, CMS intends to establish separate single payment amounts for each enteral nutrient and supply HCPCS code – rather than a bundled payment amount for enteral nutrients and related supplies.

2. Reduction in Rental Payments

We also are concerned about CMS's proposal to reduce rental payments for enteral equipment in months 4 – 15 from 10 percent of the purchase amount (as is the case under current Medicare fee-for-service rules) to 7.5 percent of the single payment. Due to the service-intensive nature of providing enteral nutrition and the possible increased costs that new quality standards requirements will impose on suppliers, reducing the rental payment formula in addition to reducing payment through the bidding process could further impede suppliers' ability to provide high-quality products and services to Medicare beneficiaries.

E. Grandfathering of Suppliers [Payment Basis]

Abbott Recommendation: If CMS includes enteral equipment in competitive bidding, CMS should include enteral equipment in the grandfathering process.

We support CMS's proposal to allow grandfathered suppliers to continue to furnish rental items under existing rental agreements and to allow accessories and supplies used in conjunction with grandfathered rental DME to be furnished by grandfathered supplier. However, it appears under the technical regulatory language that the provision would not apply to rented *enteral* feeding pumps. It appears that the omission of enteral pumps from the grandfathering provision is an oversight since enteral pumps technically fall under the orthotics and prosthetics benefit category, rather than the DME category. Moreover, CMS provides in the CMS Medicare Claims Processing Manual that "Payment policies for these pumps generally follow the rules for capped rental items."[23] Thus it would be consistent for CMS to apply the grandfathering process to enteral feeding pumps just as it does to capped rental DME items.

Beneficiaries using enteral equipment should have the benefit of this provision, particularly because of the importance of continuity of care for these clinically-complex patients and their intensive service needs. We therefore respectfully request that CMS specifically apply the grandfathering provision to suppliers of enteral nutritionals, equipment, and supplies in the final rule.

23 Medicare Claims Processing Manual, Chapter 20, section 30.7.1.

III. Other Competitive Bidding/Payment Reform Comments

A. Physician Authorization/Treating Practitioner

Abbott Recommendation: We support CMS's proposed requirement that suppliers fill prescriptions with the brand or mode of delivery specified by the physician or prescribing clinician.

CMS proposes to allow a physician or treating practitioner to prescribe a particular brand of an item or mode of delivery of an item if he or she determines that it would avoid an adverse medical outcome for the beneficiary, and the supplier would be required to furnish the specified brand or mode of delivery. We strongly support this provision. As we have previously noted, blood glucose monitoring products and enteral products within a particular code are not interchangeable. In many cases, substitution of enteral nutrition or blood glucose monitoring products other than those specifically prescribed by the physician could lead to adverse medical outcomes. We therefore agree with CMS that physicians and practitioners need to be able to prescribe the most clinically-appropriate product for their patients, and that to prevent interference with the practice of medicine, suppliers should be prohibited from switching products without written physician authorization.

B. Conditions for Awarding Contracts/Quality Standards & Accreditation

Abbott Recommendation: We recommend that CMS establish final supplier quality standards and ensure that suppliers are accredited before implementing bidding in any region.

Quality standards are key to protecting beneficiaries in CBAs, particularly for beneficiaries with diabetes and those that rely on enteral nutrition because of the often complex clinical management of the beneficiaries' medical conditions and the critical need for ongoing beneficiary support. Quality standards are the main safeguard against suppliers submitting unreasonably low bids and then providing inferior items and/or poor beneficiary service. However, to date CMS has released only a draft contractor report on the quality standards.

CMS staff have indicated that the agency received more than 5000 comments on the draft standards, and that substantial revisions would be made in the final version. We are concerned that CMS has not provided sufficient detail regarding the proposed supplier quality standards to allow informed public comment, as is required under the Administrative Procedure Act. CMS's notice must describe the range of alternatives being considered with reasonable specificity; otherwise, interested parties will not know what to comment on, and notice will not lead to better-informed agency decision-making. See Small Refiner Lead Phase-Down Task Force v. EPA, 705 F.2d 506, 549 (D.C. Cir 1983) (holding that the EPA did not give adequate notice that it might issue a strict interim lead-content limit for leaded gasoline produced by certain small refiners and this procedural error was reversible error). CMS therefore should keep open the comment period on the Proposed Rule until after the final quality standards are issued and the public has sufficient time to review those standards and their interaction with the competitive bidding framework.

Moreover, in light of the importance of the quality standards to the whole competitive bidding program, we recommend that CMS issue the revised quality standards in proposed form and allow another comment opportunity on the quality standards. Suppliers also will need time to develop systems and train personnel to comply with these standards and to become accredited. Given the delay in releasing final quality standards, it will be difficult for suppliers to come into compliance in time for competitive bidding to be implemented in 2007. CMS should not implement competitive bidding until appropriate quality standards are in place and a sufficient number of suppliers are accredited to provide adequate services to meet beneficiary demand.

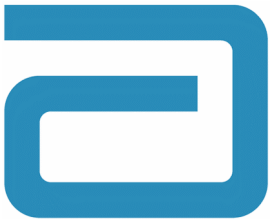
C. Conditions for Awarding Contracts/Determining the Pivotal Bid, & Determining Single Payment Amounts for Individual Items

Abbott Recommendation: We recommend that CMS establish payment amounts in the first phase of competitive bidding after excluding outlier bids, and test alternatives to the use of the median price (e.g., mean and weighted mean). CMS should exclude the bids of limited service DMEPOS suppliers (e.g., SNFs and physicians) and mail order suppliers when establishing pivotal bids and single payment amounts. CMS should only include bids of suppliers that have been accredited. CMS should establish safeguards to prevent suppliers from skewing pivotal bids and single payment amounts by bidding unrealistically low prices and then dropping out of the program.

1. Pivotal Bid and Payment Methodologies

It is critical that CMS establish a bid selection process that is equitable and that will result in payment amounts that are sustainable and compatible with access to quality care for Medicare beneficiaries. We are concerned that under the Proposed Rule, bid prices could be distorted by extremely low bids for a particular product (there is little incentive to bid very high prices since it is unlikely such a bidder would be selected as a contract supplier). CMS would achieve pricing that is more reflective of the marketplace if it did not include in its calculation of pivotal bids or single payment amounts outlier bids based on two standard deviations of all bids submitted. Likewise, CMS should weight bids by supplier capacity to prevent suppliers that expect to offer few items from having as much weight as major suppliers in an area and possibly distorting payment amounts.

Moreover, by using a median of winning bids to set the single payment amount, CMS is proposing an untested methodology under which half of "winning" bidders would actually be paid less than the amount they bid. It is doubtful that half of the winning suppliers will be willing or able to accept payment amounts below their bid price, particularly since there is such a strong incentive under the bidding framework to bid as low as possible to have the best chance of continuing to serve Medicare beneficiaries. This could have a dramatic impact on the number of suppliers that actually decide to participate in the program once the single payment amounts are announced, and subsequently could adversely impact convenient beneficiary access to suppliers. It also appears that setting payment rates at a fairly arbitrary level does not comport with the free-market dynamics that Congress envisioned when establishing competitive bidding. We therefore recommend that CMS use the first phase of competitive bidding to test alternative payment methodologies, such as using the mean or a



weighted mean, in various CBAs. This would provide important information to CMS on which to build when the program is expanded in 2009.

2. Inclusion of Limited Service, Mail Order, or Unaccredited Bidders

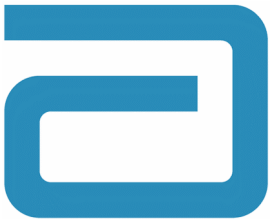
There also is a danger that the pivotal bids and single payment amounts could be distorted by the inclusion of bidders providing a restricted set of services, by bidders who are not accredited, or by "low-ball" bidders who can simply leave the program if not satisfied with the ultimate reimbursement rates. This in turn could deny legitimate suppliers the ability to participate in the program, render it difficult to establish sufficient supplier capacity, and ultimately diminish the availability of DMEPOS items and services for beneficiaries.

CMS contemplates including all bids submitted by all suppliers when determining the pivotal bid. CMS then would consider all supplier bids that are at or below the pivotal bid when determining the single payment amount for an item. However, CMS is proposing separate requirements for some bidding suppliers that would impact their cost of doing business and could distort bidding amounts.

For instance, CMS proposes that physicians who are also DMEPOS suppliers would not be required to furnish DMEPOS items to beneficiaries in competitive bidding areas who are not their patients if they choose not to function as commercial suppliers. Likewise, CMS states that a SNF would not be required to furnish competitively bid items to beneficiaries outside of the SNF if it elects not to furnish as a commercial supplier. On the other hand, non-physician and non-SNF suppliers must agree to furnish competitively bid items to all beneficiaries who maintain a permanent residence or who visit the competitive bidding area and request those items from the contract supplier. Because commercial suppliers would not be permitted to select or restrict their customers, as a SNF or physician could, they would have very different costs of doing business. Moreover, SNFs would not be responsible for complying with the full set of DMEPOS quality standards, as previously discussed, which again would widen the differences in their costs compared to commercial suppliers. SNF and physician bid prices thus should not be directly compared to the bids of retail suppliers. The most equitable policy would be to exclude SNF and physician bids from consideration when determining the pivotal bid and the single payment amount.

Similarly, as noted previously, CMS should not to consider mail order suppliers' bids in the same pool as retail supplier bids, since mail order suppliers would not be subject to the same initial delivery, set-up, and beneficiary education/training requirements as other suppliers. Indeed, mail order suppliers would be prohibited from providing these services under the draft DMEPOS supplier standards. Because CMS is imposing narrower service-related costs on mail order suppliers, it would be unreasonable and unfair to include their bids in the determination of pivotal amounts or single payment amounts. Including mail order suppliers – with their reduced responsibilities and therefore reduced costs -- in the same bidding pool as retail suppliers also would distort the median bids and make it more likely that small retail suppliers would have to accept a single payment amount that is below the amount that they bid.

In addition, compliance with quality standards – promoted through supplier accreditation – is a significant factor in determining bid amounts. The costs associated with such compliance are unknown since CMS has not yet released final quality standards. CMS states that it will not award a contract to an entity unless the entity meets applicable quality standards, but CMS



may grant a grace period for suppliers that have not had sufficient time to obtain accreditation before submitting a bid. If a supplier does not then successfully attain accreditation, CMS would suspend or terminate the supplier contract. CMS also states that it would ensure that suppliers meet quality and financial standards prior to arraying the bids for determination of the pivotal bid. However, CMS is silent on whether suppliers benefiting from a grace period would be included in the pivotal bid determination or single payment amounts. Because such suppliers have not demonstrated their compliance with supplier quality standards, and because they ultimately may not be accredited or participate in the bidding program, CMS should not consider their bids when setting the pivotal bid or single payment amounts.

Moreover, the proposed rule is silent on whether each individual retail location of a chain supplier will be allowed to submit a bid for the same product category in a particular CBA if each location has its own supplier number. We are concerned that allowing one parent company to essentially bid multiple times – either at the same or different bid prices -- would distort the bidding process by overly weighting one company's bids and result in skewed payment amounts. Moreover, due to the parent company's contracting arrangements, it could potentially limit the range of items available to beneficiaries and clinicians within a particular HCPCS code. CMS therefore should clarify in the final rule that even if a corporate entity has multiple supplier numbers, it may submit only one bid for a product category in a CBA.

3. Impact of Winning Bidders Dropping Out of Program

Finally, we are concerned that suppliers may bid prices below which they actually can afford to supply covered items in the hopes of being a winning bidder and in the expectation that prices will be brought up by other, higher bidders. If the single price ends up insufficient for such suppliers, they may simply leave the program. Yet the unrealistic, unsustainable prices they submitted would continue to have an impact on other suppliers through the artificially low payments for the three years of the contract. Such unrealistically low prices could make it difficult to attract new suppliers to fill the capacity resulting from the low-ball bidder leaving the program. Under the Proposed Rule, there is little drawback to a supplier adopting such a low-ball strategy, despite the impact it has on payment levels, capacity calculations, and beneficiary service. CMS should consider more effective ways to prevent such manipulation of the system.

We also recommend that CMS monitor reductions in the number of suppliers for a particular item, which could indicate an unrealistic and unsupportable payment amount (notwithstanding CMS's plans to try to recruit more suppliers to replace those that leave the program). If reductions in supplier capacity reaches a certain threshold, such as a 10 percent difference in the original winning suppliers, CMS should rebid the products rather than continue to attempt to find suppliers willing to accept a price that clearly does not reflect what the market as a whole can support.

D. Payment Basis: Authority to Adjust Payments in Other Areas

Abbott Recommendation: We recommend that CMS not extend pricing developed in competitive bidding to any other areas until a complete impact analysis can be performed and mandated reports have been submitted. After such analysis has been completed, CMS should issue a proposed rule which would offer the public an

opportunity to comment on standards for any extension of pricing from competitive bidding in other areas.

CMS proposes to exercise its authority to use payment information determined under competitive bidding to adjust fee schedule payments for items that are not in CBAs. However, the agency has not yet announced a detailed methodology for such a process.

Given that the scope of this provision would extend far beyond the limited number of competitive bidding areas, CMS should establish this policy through a separate rulemaking that spells out the criteria for making fee schedule adjustments. We recommend that CMS adopt as a minimum standard the procedural safeguards included in the final inherent reasonableness rule,[24] which provides among other things that:

- Payments may not be reduced by more than 15 percent in a given year (except in extraordinary situations and after additional procedural safeguards are observed);
- CMS must publish in the Federal Register proposed and final notices announcing the new payment limits prior to adoption;
- If the dollar impact of an adjustment exceeds $100 million in any one year, CMS must publish in the Federal Register an impact statement, including an analysis of the effect of quality of care, access issues, and the financial viability of suppliers in the marketplace;
- If CMS makes adjustments that have a significant effect on a substantial number of small entities, it must publish an analysis in compliance with the Regulatory Flexibility Act;
- In no case may the effective date of an adjustment be sooner than 60 days after publication of the final notice; and
- CMS must ensure the use of valid and reliable data.

Moreover, we recommend that CMS not apply competitive bidding prices in other areas until the results of the first phase of competitive bidding are fully assessed. Specifically, CMS should not extend competitive bidding prices beyond CBAs until: (1) the Government Accountability Office ("GAO") issues its report on the impact of competitive acquisition on DME on patients, suppliers, and manufacturers of medical equipment, and (2) the Secretary submits its report to Congress on program savings, access to and quality of items and services, and beneficiary satisfaction. It would be imprudent to extend the reach of competitive bidding prices without the benefit of the Congressionally-mandated analyses, which will assess how competitive acquisition affects beneficiary access to DMEPOS along with product quality and services related to DMEPOS.

24 67 Fed. Reg. 76,684 (December 13, 2002).

E. Other Competitive Bidding Issues

1. Education and Outreach

We commend CMS for proposing extensive supplier and beneficiary outreach and education initiatives as part of the competitive bidding program. Such efforts will be an important component in ensuring the smooth implementation of the new distribution and payment structure. We also urge CMS to include physicians and other clinicians in these outreach and education efforts, given their important role in prescribing the most appropriate products for their patients.

2. Monitoring and Complaint Services for the Competitive Bidding Program

We support CMS's plans to establish a formal complaint monitoring system to address complaints in each CBA. We believe that the information collected will be particularly helpful to CMS as it prepares to expand competitive bidding to additional areas in subsequent phases of the program.

We recommend that CMS include in its complaint monitoring system the collection of brand-specific information on medical complications related to competitively-bid equipment, especially for blood glucose monitoring products and enteral products if they are included in competitive bidding because of the potential for complications with these items. Moreover, CMS should collect data on suppliers that do not successfully furnish particular brands of equipment specified by practitioners. We recommend that CMS release timely reports on the results of its complaint monitoring system to inform public dialogue and analysis regarding the competitive bidding program and to ensure adequate data is available to guide development of subsequent phases of the program.

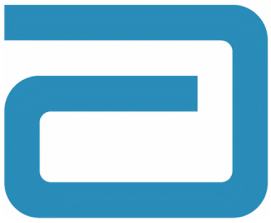
3. Miscellaneous Codes

CMS does not discuss how it would consider miscellaneous equipment and supply codes in competitive bidding. Because miscellaneous codes can encompass a wide range of products at a wide range of prices, and because suppliers would not be able to predict which brands of miscellaneous products they would need to supply during a three-year bidding cycle, we recommend that CMS exclude miscellaneous codes from competitive bidding.

F. Gap Filling Payment Methodology

Abbott Recommendation: CMS should issue a separate rulemaking to clarify and refine the gap fill pricing methodology, and should not adopt "functional technology assessments" as currently proposed. The new rulemaking should set forth the possible criteria, evidentiary standards, and procedural safeguards CMS proposes to use in performing functional technology assessments.

CMS is proposing significant revisions to its pricing policy for DMEPOS fee schedule amounts. Instead of a "gap fill" process that has been used since 1989, CMS is proposing to base payment for new items in part on a new "functional technology assessment" process, which takes into account one or more of the following factors: (1) functional assessment; (2) price



comparison analysis; and/or (3) medical benefit assessment. CMS also is proposing to use the new technology assessment process to adjust prices already established using the gap-filling methodology. Further, CMS indicates that these analyses also will be used in the HCPCS coding process and potentially the Medicare coverage process.

We are concerned about CMS raising this major pricing reform (and potentially coding and coverage policy changes) in the context of the DMEPOS competitive bidding rule, since the scope of this proposed policy goes far beyond the statutory competitive bidding authority. Gap-filling is an important and complex process with an impact on thousands of medical products, and it deserves appropriate attention apart from the competitive bidding rule. Given the impact the proposed pricing policy would have on new and established technologies and the significant changes already planned in 2007 as a result of competitive bidding, CMS should not adopt any changes in the gap filling methodology until at least 2008.

If CMS decides to pursue this policy, a separate, detailed proposed rule should be issued with an opportunity for public comment. CMS would need to provide much greater specificity than it has in the context of the proposed competitive bidding rule, since CMS has failed to define key concepts and left important questions unanswered, such as:

- What CMS means by "significantly improved clinical outcomes";
- What clinical data CMS would review;
- How the agency would determine what products are "similar" for price comparison purposes;
- What timelines of data would be utilized in such analyses;
- How CMS would define and determine "effectiveness";
- What procedural safeguards CMS would employ in making functional assessment determinations, such as how the agency would notify manufacturers and beneficiaries regarding pending decisions and what opportunities would be made available for submitting evidence and comments;
- What procedural and evidentiary standards *carriers* would be required to follow in making such functional assessments;
- What the relationship would be regarding the functional assessment process and CMS's current coverage process, as it appears the proposed policy would duplicate a number of functions of the CMS coverage group;
- How the process would interact with the current HCPCS coding process, including the potential impact on transparency of coding decisions (e.g., public meetings and notification of pending decisions); and
- How CMS would ensure that its new policies would not further extend the timelines for coding, coverage, and reimbursement decisions.

Moreover, if CMS considers changes to the gap-filling policy in the future, CMS should ensure, through Open Door Forums and other means, that suppliers, clinicians, the medical technology community, and beneficiaries are fully consulted on potentially dramatic changes in Medicare coverage, coding, and reimbursement policies.

We recommend that CMS proceed cautiously in this area, given its potentially significant impact on coding, coverage, and payment policy, and ultimately is effect on beneficiary access to innovative medical technologies.

G. Regulatory Impact Analysis

We are concerned that CMS may underestimate the impact on of the Proposed Rule on beneficiary access to their choice of supplier. While CMS acknowledges that "competitive bidding may result in some beneficiaries needing to switch from their current supplier if their current supplier is not selected for competitive bidding," CMS states that it expects this need for switching to be "minimal." We believe this severely underestimates the impact of the reduced choice of supplier. CMS expects only half of bidding suppliers to be selected, which undoubtedly will result in restricted beneficiary choice of suppliers. Moreover, only limited types of DMEPOS are eligible for the grandfathering provision. We believe CMS should reassess its estimates on beneficiary access and ensure that the final rule promotes the widest beneficiary choice of suppliers.

We also seek to ensure that CMS provide realistic estimates of the administrative costs associated with the competitive bidding program, since it will be essential to determine the extent to which administrative costs offset the savings to the program resulting from reduced Medicare reimbursement rates. CMS expects bidding-related costs to suppliers to reach over $36 million in just the first round of bidding, and that CMS and its contractors will have approximately $1 million in immediate fixed costs for startup and system changes. CMS also will incur maintenance costs and bid solicitation and evaluation costs, but the agency does not quantify those costs because those costs "will ultimately depend on number of suppliers that chose to submit bids." We believe that CMS should provide more constructive information on these expected costs.

Moreover, we believe that any evaluation or estimates of Medicare program savings should include an analysis of offsetting increases in hospital and other Part A costs associated with adverse clinical outcomes related to competitive bidding. Specifically, CMS should compare Part A spending in CBAs to spending in comparable areas that are not subject to competitive bidding to determine if the new program is having unintended, adverse impacts requiring the need for hospital care. Such findings should be made publicly available.

Likewise, as part of its initial and ongoing impact analyses, we recommend that CMS monitor the impact of competitive bidding on Medicaid beneficiaries and privately-insured individuals. We are concerned that many suppliers who are not winning Medicare bidders will not be able to continue supplying DMEPOS in competitive bidding areas, which would affect the availability of needed medical equipment and supplies for the non-Medicare population.

* * * *

In conclusion, we believe that enteral and diabetes products are poor candidates for the first round of the competitive bidding program, as detailed above, and should qualify for exclusion. If, however, CMS seeks to subject enteral and diabetes products to competitive bidding in any later phases, then we urge CMS to adopt the protections and qualifications as described in our comments above.

We appreciate your commitment to developing the competitive bidding program in a way that protects beneficiaries and promotes efficiency in the Medicare program. We trust that our comments provide constructive information for CMS to consider in adopting the final competitive bidding rule. Given the importance of this issue to beneficiaries with diabetes and those that rely on enteral equipment, we would appreciate the opportunity to meet with your staff to discuss the impact on these two specific patient groups and the special operational issues that would need to be adopted to safeguard their medical care. I will be in touch with your office to arrange a meeting. In the meantime, please feel free to call on me if you would have any questions.

Sincerely,

Virginia Tobiason
Senior Director
Corporate Reimbursement